

# EXHIBIT 14

## Continued

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number	15705172
	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	AVN-008CN41

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1	Laboratory Notebook Entry (Exon 51 Experiments): RT-PCR Analysis of 8036 Cells, Pages 2, Exhibit Number 1179 filed in Interferences 106,007 and 106,008 on February 16, 2015.
2	Laboratory Notebook Entry (Exon 51 Experiments): RT-PCR Analysis of KM155.C25 Cells, Pages 2, Exhibit Number 1178 filed in Interferences 106,007 and 106,008 on February 16, 2015.
3	Laboratory Notebook Entry (Exon 51 Experiments): Transfection of 8036 Cells, Pages 1, Exhibit Number 1172 filed in Interferences 106,007 and 106,008 on February 16, 2015.
4	Laboratory Notebook Entry (Exon 51 Experiments): Transfection of KM155.C25 Cells, Pages 1, Exhibit Number 1171 filed in Interferences 106,007 and 106,008 on February 16, 2015.
5	Laboratory Notebook Entry (Exon 53 Experiments): RT-PCR Analysis of KM155.C25 Cells, Pages 2, Exhibit Number 1180 filed in Interferences 106,007 and 106,008 on February 16, 2015.
6	Laboratory Notebook Entry (Exon 53 Experiments): RT-PCR Analysis of R1809 Cells, Pages 2, Exhibit Number 1181 filed in Interferences 106,007 and 106,008 on February 16, 2015.
7	Laboratory Notebook Entry (Exon 53 Experiments): Transfection of KM155.C25 Cells, Pages 1, Exhibit Number 1173 filed in Interferences 106,007 and 106,008 on February 16, 2015.
8	Laboratory Notebook Entry (Exon 53 Experiments): Transfection of R1809 Cells, Pages 1, Exhibit Number 1174 filed in Interferences 106,007 and 106,008 on February 16, 2015.
9	Claims from US Application No. 11/233,495, 6 pages, dated September 21, 2005 (Exhibit Number 2068 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
10	Laboratory Notebook Entry: General RNA recovery, Pages 2, Exhibit Number 1176 filed in Interferences 106,007 and 106,008 on February 16, 2015.
11	Laboratory Notebook Entry: Lab-on-a-Chip Analysis, Pages 3, Exhibit Number 1184 filed in Interferences 106,007 and 106,008 on February 16, 2015.

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12	Larsen et al., "Antisense properties of peptide nucleic acid," Biochim. Et Biophys. Acta, Vol. 1489, pp. 159-166 (1999), Exhibit Number 1190 filed in Interferences 106,007 and 106,008 on February 17, 2015.
13	Letter from the FDA to Sarepta Therapeutics, Inc., Re: ACCELERATED APPROVAL for the use of Exondys 51 (eteplirsen), FDA Reference ID: 3987286, dated September 19, 2016, 11 pages.
14	Letter to the U.S. Food and Drug Administration, (Dr. Billy Dunn, M.D. Director Division of Neurology Products, Office of Drug Evaluation 1, Center for Drug Evaluation and Research), for The Peripheral and Central Nervous System Advisory Committee Meeting (AdComm) supporting approval of eteplirsen, dated February 24, 2016, 4 pages.
15	Letter to the U.S. Food and Drug Administration, (Dr. Janet Woodcock, M.D. Director, CDER), from The Congress of The United States regarding Duchenne muscular dystrophy, dated February 17, 2016, 7 pages.
16	List of Publications for Matthew J. A. Wood, M.D., D. PHIL., 11 pages, (Exhibit Number 2124 filed in interferences 106,007 and 106,008 on February 17, 2015).
17	LIU, Hong-Xiang et al., "Identification of functional exonic splicing enhancer motifs recognized by individual SR proteins," Genes & Development, Vol. 12:1998-2012 (1998)
18	Lu et al, "Massive Idiosyncratic Exon Skipping Corrects the Nonsense Mutation in Dystrophic Mouse Muscle and Produces Functional Revertant Fibers by Clonal Expansion," THE JOURNAL OF CELL BIOLOGY, Vol. 148(5): 985-995, March 6, 2000 ("Lu et al.") (Exhibit Number 1082 filed in interferences 106008, 106007 on December 23, 2014)
19	LU, Qi Long et al., "Functional amounts of dystrophin produced by skipping the mutated exon in the mdx dystrophic mouse," Nature Medicine, Vol. 9(8):1009-1014 (2003)
20	LU, Qi-long et al., "What Can We Learn From Clinical Trials of Exon Skipping for DMD?" Molecular Therapy - Nucleic Acids, Vol. 3:e152, doi:10.1038/mtna.2014.6, 4 pages (2014)
21	Lyophilisation of Oligonucleotides, Pages 2, Exhibit Number 1133 filed in Interferences 106,007 and 106,008 on February 17, 2015.
22	MANN, Christopher J. et al., "Antisense-induced exon skipping and synthesis of dystrophin in the mdx mouse," PNAS, Vol. 98(1):42-47 (2001)



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23	MANN, Christopher J. et al., "Improved antisense oligonucleotide induced exon skipping in the mdx mouse model of muscular dystrophy," The Journal of Gene Medicine, Vol. 4:644-654 (2002)
24	MANNINO, Raphael J. et al., "Liposome Mediated Gene Transfer," BioTechniques, Vol. 6(7):682-690 (1988)
25	Manual of Patent Examining Procedure 2308.02 (6th ed., rev. 3, July 1997), (University of Western Australia Exhibit 2143, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-2).
26	Manzur A, et al., "Glucocorticoid corticosteroids for Duchenne muscular dystrophy," Cochrane Database Syst Rev. 2004;(2):CD003725.
27	MARSHALL, N.B. et al., "Arginine-rich cell-penetrating peptides facilitate delivery of antisense oligomers into murine leukocytes and alter pre-mRNA splicing," Journal of Immunological Methods, Vol. 325:114-126 (2007)
28	Mathews et al., "Expanded Sequence Dependence of Thermodynamic Parameters Improves Prediction of RNA Secondary Structure," J. Mol. Biol. 288:911-940 (1999), (University of Western Australia Exhibit 2131, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-31).
29	Mathews et al., "Expanded Sequence Dependence of Thermodynamic Parameters Improves Prediction of RNA Secondary Structure," J. Mol. Biol., Vol. 288, pp. 911-940 (1999), Exhibit Number 1212 filed in Interferences 106,007 and 106,008 on February 17, 2015.
30	MATSUO, Masafumi et al., "Exon Skipping during Splicing of Dystrophin mRNA Precursor due to an Intraexon Deletion in the Dystrophin Gene of Duchenne Muscular Dystrophy Kobe," J. Clin. Invest., Vol. 87:2127-2131 (1991)
31	MATSUO, Masafumi et al., "Treatment of Duchenne Muscular Dystrophy with Oligonucleotides against an Exonic Splicing Enhancer Sequence," Basic Appl. Myol., Vol. 13(6):281-285 (2003)
32	MATSUO, Masafumi, "Duchenne and Becker Muscular Dystrophy: From Gene Diagnosis to Molecular Therapy," JUBMB Life, Vol. 53:147-152 (2002)
33	MATSUO, Masafumi, "Duchenne/Becker muscular dystrophy: from molecular diagnosis to gene therapy," Brain & Development, Vol. 18:167-172 (1996)

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34	MATTEUCCI, Mark, "Structural modifications toward improved antisense oligonucleotides," Perspectives in Drug Discovery and Design, Vol. 4:1-16 (1996)
35	Mazzone E, et al. "Functional changes in Duchenne muscular dystrophy: a 12-month longitudinal cohort study," Neurology 2011;77(3):250-6.
36	MCCARVILLE, M. Beth et al., "Rhabdomyosarcoma in Pediatric Patients: The Good, the Bad, and the Unusual," AJR, Vol. 176:1563-1569 (2001) (Exhibit Number 1034 filed in interferences 106008, 106007 on November 18, 2014)
37	McCLOREY, G. et al., "Antisense oligonucleotide-induced exon skipping restores dystrophin expression in vitro in a canine model of DMD," Gene Therapy, Vol. 13:1373-1381 (2006)
38	McCLOREY, G. et al., "Induced dystrophin exon skipping in human muscle explants," Neuromuscular Disorders, Vol. 16:583-590 (2006)
39	McCLOREY, Graham et al., "Splicing intervention for Duchenne muscular dystrophy," Current Opinion in Pharmacology, Vol. 5:529-534 (2005)
40	McDonald CM, et al., "Profiles of Neuromuscular Diseases, Duchenne muscular dystrophy," Am J Phys Med Rehabil 1995;74:S70-S92
41	McDonald CM, et al., "The 6-minute walk test as a new outcome measure in Duchenne muscular dystrophy," Muscle Nerve 2010;41:500-10.
42	McDonald CM, et al., "The 6-minute walk test in Duchenne/Becker muscular dystrophy: longitudinal observations," Muscle Nerve 2010;42: 966-74.
43	Mendell JR et al., "Evidence-based path to newborn screening for Duchenne muscular Dystrophy," Ann Neurol 2012;71:304-13.
44	Mendell JR, et al., "Dystrophin immunity revealed by gene therapy in Duchenne muscular dystrophy," N Engl J Med 2010;363:1429-37.

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45	Mendell JR, et al., "Randomized, double-blind six-month trial of prednisone in Duchenne's muscular dystrophy," N Engl J Med 1989;320:1592-97.
46	MENDELL, Jerry R. et al., "Eteplirsen for the Treatment of Duchenne Muscular Dystrophy," Ann. Neurol., Vol. 74:637-647 (2013) (Exhibit Number 2058 filed in interferences 106008, 106013, 106007 on November 18, 2014)
47	MENDELL, Jerry R. et al., "Eteplirsen in Duchenne Muscular Dystrophy (DMD): 144 Week Update on Six-Minute Walk Test (6MWT) and Safety," slideshow, presented at the 19th International Congress of the World Muscle Society, 17 pages (2014) (Exhibit Number 2059 filed in interferences 106008, 106013, 106007 on November 18, 2014)
48	MENDELL, Jerry R. et al., "Gene therapy for muscular dystrophy: Lessons learned and path forward," Neuroscience Letters, Vol. 527:90-99 (2012)
49	Merlini L, et al., "Early corticosteroid treatment in 4 Duchenne muscular dystrophy patients: 14-year follow-up," Muscle Nerve 2012;45:796-802.
50	Mfold illustrations for Exon 51 and Exon 53 with varying amounts of intron sequence, (University of Western Australia Exhibit 2132, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-2).

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
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1	Sarepta Briefing Information for the April 25, 2016 Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee, Eteplirsen Briefing Document, NDA 206488, 186 pages.
2	Sarepta Presentation at Peripheral and Central Nervous System Drugs Advisory Committee, April 25, 2016, 133 pages
3	Sarepta Press Release, Sarepta Issues Statement on Advisory Committee Outcome for Use of Eteplirsen in the Treatment of Duchenne Muscular Dystrophy, April 25, 2016, 2 pages
4	Sarepta Therapeutics Press Release, dated January 12, 2015, Exhibit Number 1119 filed in interferences 106,007 and 106,008 on February 17, 2015.
5	Sarepta Therapeutics, Advisory Committee Briefing Materials: Available for Public Release, "Peripheral and Central Nervous System Drugs Advisory Committee," Eteplirsen Briefing Document Addendum, NDA 206488, pages 1-9, dated January 22, 2016.
6	Sarepta Therapeutics, Advisory Committee Briefing Materials: Available for Public Release, "Peripheral and Central Nervous System Drugs Advisory Committee," Eteplirsen Briefing Document, NDA 206488, pages 1-166, dated January 22, 2016.
7	Sarepta Therapeutics, Inc. News Release, "Sarepta Therapeutics Announces FDA Accelerated Approval of EXONDYS 51™ (eteplirsen) injection, an Exon Skipping Therapy to Treat Duchenne Muscular Dystrophy (DMD) Patients Amenable to Skipping Exon 51," September 19, 2016, 2 pages.
8	Sarepta, "AVI BioPharma Initiates Dosing in Phase 2 Study of Eteplirsen in Duchenne Muscular Dystrophy Patients," press release, 4 pages, dated August 15, 2011 (Exhibit Number 2082 filed in interferences 106008, 106013, 106007 on November 18, 2014)
9	Sarepta, "Sarepta Therapeutics Announces Eteplirsen Demonstrates Continued Stability on Walking Test through 120 Weeks in Phase Iib Study in Duchenne Muscular Dystrophy," press release, 3 pages, dated January 15, 2014 (Exhibit Number 2034 filed in interferences 106008, 106013, 106007 on November 18, 2014)
10	Sarepta, "Sarepta Therapeutics Reports Long-Term Outcomes through 144 Weeks from Phase IIb Study of Eteplirsen in Duchenne Muscular Dystrophy," press release, <a href="http://investorrelations.sarepta.com/phoenix.zhtml?c=64231&amp;p=irol-newsArticle&amp;id=1946426">http://investorrelations.sarepta.com/phoenix.zhtml?c=64231&amp;p=irol-newsArticle&amp;id=1946426</a> , 4 pages, dated July 10, 2014
11	Scully, Michele et al., "Review of Phase II and Phase III Clinical Trials for Duchenne Muscular Dystrophy", Expert Opinion on Orphan Drugs, Vol.1(1):33-46 (2013)



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12	Second Preliminary Amendment filed in US Application No. 13/550,210, 5 pages, dated January 3, 2013 (Exhibit Number 2062 filed in interferences 106008, 106013, 106007 on November 18, 2014)
13	Second Written Opinion for Application No. PCT/AU2010/001520, 7 pages, dated October 13, 2011
14	Semi Quantitative Lab-on-Chip Analysis of Second PCR Product, Pages 1, Exhibit Number 1183 filed in Interferences 106,007 and 106,008 on February 16, 2015.
15	Sequence Listing - Serial No. 13/550,210, as filed July 16, 2012 (9 pages), Exhibit Number 1205 filed in Interferences 106,007 and 106,008 on February 17, 2015.
16	Sequence of Exon 46 of Dystrophin Gene, 1 page
17	Sequence of Exon 51 of Dystrophin Gene, 1 page
18	Shabanpoor et al., "Bi-specific splice-switching PMO oligonucleotides conjugated via a single peptide active in a mouse model of Duchenne muscular dystrophy," Nucleic Acids Res., pp. 1-11 (December, 2014), Exhibit Number 1114 filed in interferences 106,007 and 106,008 on February 17, 2015.
19	SHAPIRO, Marvin B. et al., "RNA splice junctions of different classes of eukaryotes: sequence statistics and functional implications in gene expression," Nucleic Acids Research, Vol. 15(17):7155-7174 (1987)
20	SHERRATT, Tim G. et al., "Exon Skipping and Translation in Patients with Frameshift Deletions in the Dystrophin Gene," Am. J. Hum. Genet., Vol. 53:1007-1015 (1993)
21	SHIGA, Nobuyuki et al., "Disruption of the Splicing Enhancer Sequence within Exon 27 of the Dystrophin Gene by a Nonsense Mutation Induced Partial Skipping of the Exon and Is Responsible for Becker Muscular Dystrophy," J. Clin. Invest., Vol. 100(9):2204-2210 (1997)
22	SHIMIZU, Miho et al., "Oligo(2'-O-methyl)ribonucleotides Effective probes for duplex DNA," FEBS Letters, Vol. 302(2):155-158 (1992) (Exhibit Number 1035 filed in interferences 106008, 106007 on November 18, 2014)



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23	Siemens Healthcare Diagnostics, Inc. v. Enzo Life Sciences, Inc., 2013 WL 4411227, *11 [Parallel cite: U.S.D.C., D. Mass., Civil No. 10-40124-FDS], Decided Aug. 14, 2013 (12 pages); [Cited as: 2013 WL 4411227], Exhibit Number 1210 filed in Interferences 106,007 and 106,008 on February 17, 2015.
24	SIERAKOWSKA, Halina et al., "Repair of thalassemic human beta-globin mRNA in mammalian cells by antisense oligonucleotides," Proc. Natl. Acad. Sci. USA, Vol. 93:12840-12844 (1996)
25	Sontheimer et al., "Metal ion catalysis during group II intron self-splicing: parallels with the spliceosome," Genes & Development, Vol. 13, pp. 1729-1741 (1999), Exhibit Number 1195 filed in Interferences 106,007 and 106,008 on February 17, 2015.
26	Sontheimer et al., "Three Novel Functional Variants of Human U5 Small Nuclear RNA," Vol. 12, No. 2, pp. 734-746 (Feb., 1992), Exhibit Number 1194 filed in Interferences 106,007 and 106,008 on February 17, 2015.
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37	SUMMERTON, James et al., "Morpholino and Phosphorothioate Antisense Oligomers Compared in Cell-Free and In-Cell Systems," Antisense & Nucleic Acid Drug Development, Vol. 7:63-70 (1997)
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Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
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1	Transcript of 2nd Deposition of Erik J. Sontheimer, Ph.D., dated March 12, 2015, (Academisch Ziekenhuis Leiden Exhibit 1231, filed April 3, 2015 in Interference 106007 and 106008, pages 1-185).
2	Transcript of 2nd Deposition of Matthew J.A. Wood, M.D., D. Phil, dated March 5, 2015, (Academisch Ziekenhuis Leiden Exhibit 1230, filed April 3, 2015 in Interference 106007 and 106008, pages 1-117).
3	Transcript of December 12, 2014 Teleconference with Administrative Patent Judge Schafer (rough draft) (previously filed in Int. No. 106,008 as Ex. 2114), Pages 28 Exhibit Number 1001 filed in Interference 106,013 on February 17, 2015.
4	Transcript of the January 21, 2015 deposition of Erik Sontheimer, Ph.D., Patent Interference Nos. 106,007 and 106,008, 98 pages, dated January 21, 2015 (Exhibit Number 2122 filed in interferences 106,007 and 106,008 on February 17, 2015).
5	Transcript of the March 11, 2015 deposition of Judith van Deutekom, Ph.D., (University of Western Australia Exhibit 2141, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-168).
6	Transcript of the March 12, 2015 deposition of Erik J. Sontheimer, Ph.D., (University of Western Australia Exhibit 2142, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-183).
7	Transcript of the March 5, 2015 deposition of Matthew J. A. Wood, M.D., D. PHIL., (University of Western Australia Exhibit 2146, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-115).
8	Transfection of AON, Pages 1, Exhibit Number 1170 filed in Interferences 106,007 and 106,008 on February 16, 2015.
9	U.S. Food and Drug Administration Presentation at Peripheral and Central Nervous System Drugs Advisory Committee, April 25, 2016, 178 pages.
10	U.S. Food and Drug Administration Statement, dated December 30, 2014 (2 pages), Exhibit Number 1204 filed in Interferences 106,007 and 106,008 on February 17, 2015.
11	U.S. Patent Application No. 12/198,007, as-filed August 25, 2008 ("the '007 Application") (Exhibit Number 1073 filed in interferences 106008, 106007 on December 23, 2014)

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12	U.S. Patent Application No. 12/976,381, as-filed December 22, 2010 ("the '381 Application") (Exhibit Number 1074 filed in interferences 106008, 106007 on December 23, 2014)
13	U.S. Patent Application Publication No. 2001/0056077 ("Matsuo") (Exhibit Number 1080 filed in interferences 106008, 106007 on December 23, 2014)
14	U.S. Patent Application Publication No. 2002/0049173 ("Bennett et al.") (Exhibit Number 1081 filed in interferences 106008, 106007 on December 23, 2014)
15	U.S. Patent No. 5,190,931 ("the '931 Patent") (Exhibit Number 1069 filed in interferences 106008, 106007 on December 23, 2014)
16	U.S. Patent No. 7,001,761 (the "Xiao" Patent) (Exhibit Number 1070 filed in interferences 106008, 106007 on December 23, 2014)
17	University of Western Australia Objections to Opposition Evidence, served on February 24, 2015 filed in Interference No. 106,007, Exhibit 2150, filed April 10, 2015 in Interference Nos. 106007 and 106008, pages 1-15.
18	University of Western Australia Objections to Opposition Evidence, served on February 24, 2015, filed in Interference No. 106,008, Exhibit 2151, filed April 10, 2015, in Interference Nos. 106007 and 106008, pages 1-15.
19	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision - Motions - 37 C.F.R. § 41.125(a), filed in Patent Interference No. 106008, September 20, 2016, pages 1-20 (Doc 480)
20	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision - Motions - 37 CFR § 41.125(a) (Substitute), filed in Patent Interference No. 106007, May 12, 2016, pages 1-53 (Doc 476)
21	University of Western Australia v. Academisch Ziekenhuis Leiden, Judgment - Motions - 37 C.F.R. § 41.127 filed in Patent Interference No. 106008, September 20, 2016, pages 1-3 (Doc 481)
22	University of Western Australia v. Academisch Ziekenhuis Leiden, Judgment - Motions - 37 CFR § 41.127, filed in Patent Interference No. 106007, April 29, 2016, pages 1-3 (Doc 474)



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23	European Response, Application No. 13160338.3, 4 pages, dated June 26, 2014 (Exhibit Number 2085 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
24	University of Western Australia v. Academisch Ziekenhuis Leiden, Redecaration - 37 CFR 41.203(c), filed in Patent Interference No. 106007, April 29, 2016, pages 1-2 (Doc 473)
25	University of Western Australia v. Academisch Ziekenhuis Leiden, Withdrawal and Reissue of Decision on Motions, filed in Patent Interference No. 106007, May 12, 2016, pages 1-2 (Doc 475)
26	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits (as of Apr. 3, 2015), filed in Patent Interference No. 106,007, April 3, 2015, pages 1-18, (Doc 423).
27	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits (as of Apr. 3, 2015), filed in Patent Interference No. 106,008, April 3, 2015, pages 1-18 (Doc 435).
28	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 18 pages, Patent Interference No. 106,007, (Doc 391), dated February 17, 2015.
29	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 18 pages, Patent Interference No. 106,008, (Doc 398), dated February 17, 2015.
30	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 3 pages, Patent Interference No. 106,013, (Doc 147), dated February 17, 2015.
31	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Notice of Service of Supplemental Evidence, 3 pages, Patent Interference No. 106,007 (Doc 414), dated March 9, 2015.
32	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Notice of Service of Supplemental Evidence, 3 pages, Patent Interference No. 106,008 (Doc 422), dated March 9, 2015.
33	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 1 (35 U.S.C. § 112(a)), 83 pages, Patent Interference No. 106,008, (Doc 400), dated February 17, 2015

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34	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 1 (35 U.S.C. § 112(a)), 93 pages, Patent Interference No. 106,007, (Doc 392), dated February 17, 2015
35	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 1 (Standing Order ¶ 203.1 and 37 C.F.R. § 41.202(a) and (e)), 20 pages, Patent Interference No. 106,013, (Doc 148), dated February 17, 2015
36	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 2 (Indefiniteness), 31 pages, Patent Interference No. 106,007, (Doc 396), dated February 17, 2015
37	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 2 (Indefiniteness), 32 pages, Patent Interference No. 106,008, (Doc 401), dated February 17, 2015
38	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 3 (35 U.S.C. § 135(b)), 44 pages, Patent Interference No. 106,008, (Doc 397), dated February 17, 2015
39	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 3 (Standing Order § 203.1 and 37 C.F.R. § 41.202(a) and (e)), 20 pages, Patent Interference No. 106,007, (Doc 389), dated February 17, 2015.
40	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. §§ 102 and 103), dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-17 (Doc 431).
41	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. §§ 102 and 103), dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-17 (Doc 424).
42	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 2 (To Deny the Benefit of AU 2004903474), dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-11(Doc 425).
43	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 2 (To Deny the Benefit of AU 2004903474), dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-12 (Doc 432).
44	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 3 (For Judgment of Unpatentability based on Myriad) dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-12 (Doc 426).

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45	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 3 (For Judgment of Unpatentability based on Myriad) dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-13 (Doc 433).
46	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 4 (In Support of Responsive Motion 4 to Add Two New Claims) dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-17 (Doc 427).
47	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 4 (In Support of Responsive Motion 4 to Add Two New Claims) dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-17 (Doc 434).
48	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Request For Oral Argument, filed in Patent Interference No. 106,007, April 10, 2015, pages 1-3 (Doc 454).
49	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Request For Oral Argument, filed in Patent Interference No. 106,008, April 10, 2015, pages 1-3 (Doc 462).
50	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Responsive Motion 4 (To Add Two New Claims), 57 pages, Patent Interference No. 106,008, (Doc 245), dated December 23, 2014.

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☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number	15705172
	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	AVN-008CN41

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45	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's List of Exhibits as of May 5, 2015, filed in Patent Interference No. 106,008, May 5, 2015, pages 1-18 (Doc 474).
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	2	5034506		1991-07-23	Summerton et al.	
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48	2636742	EP	A1	2013-09-11	ACADEMISCH ZIEKENHUIS LEIDEN		
49	2799548	EP	A1	2014-11-05	NIPPON SHINYAKU CO., LTD		
50	2801618	EP	A1	2014-11-12	Academisch Ziekenhuis Leiden		

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	1	"Efficacy Study of AVI-4658 to Induce Dystrophin Expression in Selected Duchenne Muscular Dystrophy Patients" ClinicalTrials.gov dated January 22, 2013
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10	A Comparative Study on AONs between 20 and 50 Nucleotides Designed to Induce the Skipping of Exon 53 from the Dystrophin Pre-mRNA, Pages 6, Exhibit Number 1128 filed in Interferences 106,007 and 106,008 on February 17, 2015.
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37	AON PS1959 Mass Spectrometry Data, Pages 5, Exhibit Number 1147 filed in Interferences 106,007 and 106,008 on February 16, 2015.
38	AON PS1959 UPLC Data, Pages 2, Exhibit Number 1158 filed in Interferences 106,007 and 106,008 on February 16, 2015.
39	AON PS1960 Mass Spectrometry Data, Pages 8, Exhibit Number 1148 filed in Interferences 106,007 and 106,008 on February 16, 2015.
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41	AON PS1961 Mass Spectrometry Data, Pages 5, Exhibit Number 1149 filed in Interferences 106,007 and 106,008 on February 16, 2015.
42	AON PS1961 UPLC Data, Pages 2, Exhibit Number 1160 filed in Interferences 106,007 and 106,008 on February 16, 2015.

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43	AON PS1962 Mass Spectrometry Data, Pages 7, Exhibit Number 1150 filed in Interferences 106,007 and 106,008 on February 16, 2015.
44	AON PS1962 UPLC Data, Pages 2, Exhibit Number 1161 filed in Interferences 106,007 and 106,008 on February 16, 2015.
45	AON PS1963 Mass Spectrometry Data, Pages 10, Exhibit Number 1151 filed in Interferences 106,007 and 106,008 on February 16, 2015.
46	AON PS1963 UPLC Data, Pages 2, Exhibit Number 1162 filed in Interferences 106,007 and 106,008 on February 16, 2015.
47	AON PS1964 Mass Spectrometry Data, Pages 13, Exhibit Number 1152 filed in Interferences 106,007 and 106,008 on February 16, 2015.
48	AON PS1964 UPLC Data, Pages 2, Exhibit Number 1163 filed in Interferences 106,007 and 106,008 on February 16, 2015.
49	AON PS1965 Mass Spectrometry Data, Pages 9, Exhibit Number 1153 filed in Interferences 106,007 and 106,008 on February 16, 2015.
50	AON PS1965 UPLC Data, Pages 2, Exhibit Number 1164 filed in Interferences 106,007 and 106,008 on February 16, 2015.

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Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

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15	Partial European Search Report for Application No. 10004274.6, 6 pages, dated October 2, 2012
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18	Patrick O. Brown and Tidear D. Shalon v. Stephen P.A. Fodor, Dennis W. Solas and William J. Dower: Interference Merits Panel, Interference No. 104,358, 24 pages, dated August 9, 1999 (Exhibit Number 2113 filed in interferences 106008, 106013, 106007 on November 18, 2014)
19	PCT Application as-filed for application No. PCT/NL03/00214, 64 pages, dated September 21, 2005 (Exhibit Number 2042 filed in interferences 106008, 106013, 106007 on November 18, 2014)
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21	Popplewell, et al., Design of Phosphorodiamidate Morpholino Oligomers (PMOs) For the Induction of Exon Skipping of the Human DMD Gene, DSGT Poster, 2008, 1 page.
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27	Poster Abstract Listing for The Tenth Annual Meeting of the RNA Society, held at the Banff Centre for Conferences, in Banff, Alberta, Canada, from May 24-29, 2005, (University of Western Australia Exhibit 2137, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-11).
28	Pramono, "Induction of Exon Skipping of the Dystrophin Transcript in Lymphoblastoid Cells by Transfecting an Antisense Oligodeoxynucleotide Complementary to an Exon Recognition Sequence," Biochem. and Biophys. Res. Comm., Vol. 226, pp. 445-449 (1996), Exhibit Number 1192 filed in Interferences 106,007 and 106,008 on February 17, 2015.
29	Preliminary Amendment for Application No. 12/976,381, 4 pages, dated December 22, 2010 (Exhibit Number 2066 filed in interferences 106008, 106013, 106007 on November 18, 2014)
30	Preliminary Amendment for Application No. 12/198,007, 3 pages, dated November 7, 2008 (Exhibit Number 2067 filed in interferences 106008, 106013, 106007 on November 18, 2014)
31	Prescribing Information for EXONDYS 51 (eteplirsen) Injection, dated 09/2016, 10 pages
32	Program Schedule for The Tenth Annual Meeting of the RNA Society, held at the Banff Centre for Conferences, in Banff, Alberta, Canada, from May 24-29, 2005, (University of Western Australia Exhibit 2136, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).
33	Proliferation and Differentiation of Myoblast Cultures, Pages 2, Exhibit Number 1169 filed in Interferences 106,007 and 106,008 on February 16, 2015.

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Attorney Docket Number	AVN-008CN41

34	Prosensa Press Release, dated October 10, 2014 (2 pages), Exhibit Number 1203 filed in Interferences 106,007 and 106,008 on February 17, 2015.
35	Prosensa, "GSK and Prosensa Announce Primary Endpoint Not Met in Phase III Study of Drisapersen in Patients With Duchenne Muscular Dystrophy," press release, 4 pages, dated September 20, 2013 (Exhibit Number 2039 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
36	Raz et al. v. Davis et al., Board of Patent Appeals and Interferences, Patent and Trademark Office, Int. No. 105,712, Tech. Ctr. 1600, September 29, 2011 (24 pages) (2011 WL 4568986 (Bd.Pat.App. & Interf.), Exhibit Number 1209 filed in Interferences 106,007 and 106,008 on February 17, 2015.
37	REESE, Colin B. et al., "Reaction Between 1-Arenesulphonyl-3-Nitro-1,2,4-Triazoles and Nucleoside Base Residues. Elucidation of the Nature of Side-Reactions During Oligonucleotide Synthesis," Tetrahedron Letters, Vol. 21:2265-2268 (1980)
38	REESE, Colin B. et al., "The Protection of Thymine and Guanine Residues in Oligodeoxyribonucleotide Synthesis," J. Chem. Soc. Perkin Trans. 1, pages 1263-1271 (1984)
39	Reexamination Certificate - Application No. 90/011,320, issued March 27, 2012 (Exhibit Number 1072 filed in Interferences 106008, 106007 on December 23, 2014)
40	Reply to EPO Communication dated June 26, 2014 in European Application Serial No. 13160338, (University of Western Australia Exhibit 2145, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).
41	Reply to EPO Communication dated October 21, 2014 in European Application Serial No. 12198517, (University of Western Australia Exhibit 2148, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-7).
42	Reply to EPO Communication dated October 23, 2014 in European Application Serial No. 12198485, (University of Western Australia Exhibit 2147, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-8).
43	Response to Office Action and Amendments to the Claims for Application No. 13/550,210, 10 pages, dated May 12, 2014 (Exhibit Number 2064 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
44	Rhodes et al., "BioMarin Bulks Up," BioCentury, pp. 6-8 (December, 2014), Exhibit Number 1193 filed in Interferences 106,007 and 106,008 on February 17, 2015.



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

45	RNA Isolation Using RNA-BEE, Pages 1, Exhibit Number 1175 filed in Interferences 106,007 and 106,008 on February 16, 2015.
46	ROBERTS, Roland G. et al., "Exon Structure of the Human Dystrophin Gene," Genomics, Vol. 16:536-538 (1993)
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49	Saito, T. et al., "First-in-Human Study of NS-065/NCNP-01; the Morpholino Based Antisense Oligonucleotide for Exon 53 Skipping in Duchenne Muscular Dystrophy," ASGCT meeting , May 13, 2015, Abstract [136] 1 page.
50	Saito, T. et al., "First-in-Human Study of NS-065/NCNP-01; the Morpholino Based Antisense Oligonucleotide for Exon 53 Skipping in Duchenne Muscular Dystrophy," ASGCT meeting , May 13, 2015, pages 1-11.

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**INFORMATION DISCLOSURE  
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Application Number	15705172
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First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
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Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

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<b>EFS ID:</b>	30440717
<b>Application Number:</b>	15705172
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	2879
<b>Title of Invention:</b>	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF
<b>First Named Inventor/Applicant Name:</b>	Stephen Donald WILTON
<b>Customer Number:</b>	123147
<b>Filer:</b>	Amy E. Mandragouras/Anita Costa
<b>Filer Authorized By:</b>	Amy E. Mandragouras
<b>Attorney Docket Number:</b>	AVN-008CN41
<b>Receipt Date:</b>	22-SEP-2017
<b>Filing Date:</b>	
<b>Time Stamp:</b>	17:07:55
<b>Application Type:</b>	Utility under 35 USC 111(a)

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<b>Warnings:</b>					
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53	Other Reference-Patent/App/Search documents	14857555.pdf	1169163 0a94c12f5b3cf7bc09416e8ab245c525fb760cd1	no	12
<b>Warnings:</b>					
<b>Information:</b>					
54	Information Disclosure Statement (IDS) Form (SB08)	IDSTRANS.pdf	50276 13a3bdfb712873269000ce5571df1d4f77db5354	no	8
<b>Warnings:</b>					
<b>Information:</b>					
This is not an USPTO supplied IDS fillable form					
55	Information Disclosure Statement (IDS) Form (SB08)	SB6.pdf	1089106 199adb629310f6e9470334515f86536ab3836165	no	8
<b>Warnings:</b>					
<b>Information:</b>					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
56	Information Disclosure Statement (IDS) Form (SB08)	SB8.pdf	1070179 d1cecb9ee54521a53c75ac10079b8920ed80df8	no	8
<b>Warnings:</b>					
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57	Information Disclosure Statement (IDS) Form (SB08)	SB9.pdf	1082063 2266dc70cc1a16858c72d12c6964c64eb87988ad	no	8
<b>Warnings:</b>					
<b>Information:</b>					
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58	Information Disclosure Statement (IDS) Form (SB08)	SB14.pdf	1089326 1a7b1bb58e7ccb0ac8675a762dfe4863952e4bac	no	8
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59	Information Disclosure Statement (IDS) Form (SB08)	SB1.pdf	1243016 5578a6b8352de49781eab64a3543a16fc876130a	no	32
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**Warnings:****Information:**

60	Information Disclosure Statement (IDS) Form (SB08)	SB7.pdf	1102078 876c1d3a049c64e4d8f3c7b1e4fdb52f33a24895	no	8
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<b>Total Files Size (in bytes):</b>			66097425
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**New Applications Under 35 U.S.C. 111**

**If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.**

**National Stage of an International Application under 35 U.S.C. 371**

**If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.**

**New International Application Filed with the USPTO as a Receiving Office**

**If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.**



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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
15/705,172	09/14/2017	1674	730	AVN-008CN41	2	2

CONFIRMATION NO. 2879

FILING RECEIPT



CC000000094306384

123147  
Nelson Mullins Riley & Scarborough LLP/Sarepta  
One Post Office Square  
Boston, MA 02109

Date Mailed: 09/26/2017

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Stephen Donald WILTON, Applecross, AUSTRALIA;  
Sue FLETCHER, Bayswater, AUSTRALIA;  
Graham MCCLOREY, Bayswater, AUSTRALIA;

Applicant(s)

The University of Western Australia, Crawley, AUSTRALIA;

**Power of Attorney:** The patent practitioners associated with Customer Number 123147

**Domestic Priority data as claimed by applicant**

This application is a CON of 15/274,772 09/23/2016  
which is a CON of 14/740,097 06/15/2015 PAT 9605262  
which is a CON of 13/741,150 01/14/2013 ABN  
which is a CON of 13/168,857 06/24/2011 ABN  
which is a CON of 12/837,359 07/15/2010 PAT 8232384  
which is a CON of 11/570,691 01/15/2008 PAT 7807816  
which is a 371 of PCT/AU2005/000943 06/28/2005

**Foreign Applications** (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.)  
AUSTRALIA 2004903474 06/28/2004 No Access Code Provided

**Permission to Access Application via Priority Document Exchange:** Yes

**Permission to Access Search Results:** Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

**If Required, Foreign Filing License Granted:** 09/25/2017

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/705,172**

**Projected Publication Date:** 01/04/2018

**Non-Publication Request:** No

**Early Publication Request:** No

**\*\* SMALL ENTITY \*\***

**Title**

ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

**Preliminary Class**

536

**Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications:** No

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For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific

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Title 37, Code of Federal Regulations, 5.11 & 5.15**

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<b>PATENT APPLICATION FEE DETERMINATION RECORD</b>						Application or Docket Number 15/705,172			
Substitute for Form PTO-875									
<b>APPLICATION AS FILED - PART I</b>									
(Column 1)		(Column 2)		SMALL ENTITY		OTHER THAN SMALL ENTITY			
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)		
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A			
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	300		N/A			
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A			
TOTAL CLAIMS (37 CFR 1.16(i))	2	minus 20 = *	x 40 =	0.00	OR				
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2	minus 3 = *	x 210 =	0.00					
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00					
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL		TOTAL			
<b>APPLICATION AS AMENDED - PART II</b>									
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OTHER THAN SMALL ENTITY	
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(i))	*	Minus **	x	=	OR	x	=	
	Independent (37 CFR 1.16(h))	*	Minus ***	x	=	OR	x	=	
	Application Size Fee (37 CFR 1.16(s))					OR			
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					OR			
				TOTAL ADD'L FEE		TOTAL ADD'L FEE			
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(i))	*	Minus **	x	=	OR	x	=	
	Independent (37 CFR 1.16(h))	*	Minus ***	x	=	OR	x	=	
	Application Size Fee (37 CFR 1.16(s))					OR			
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					OR			
				TOTAL ADD'L FEE		TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.									

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with 37 CFR § 1.6(a)(4).

Dated: September 26, 2017  
Electronic Signature for Amy E. Mandragouras, Esq.: /Amy E. Mandragouras, Esq./

Docket No.: AVN-008CN41  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Stephen Donald Wilton *et al.*

Application No.: 15/705,172

Confirmation No.: 2879

Filed: September 14, 2017

Art Unit: 1674

For: ANTISENSE OLIGONUCLEOTIDES FOR  
INDUCING EXON SKIPPING AND  
METHODS OF USE THEREOF

Examiner: K. Chong

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (SIDS)**

Dear Sir:

In compliance with 37 C.F.R. § 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the document listed on the attached PTO/SB/08. In accordance with 37 C.F.R. § 1.98(a)(2)(i)-(iv), Applicant has not included a copy of the U.S. Patent Publication.

It is respectfully requested that the document listed on the PTO/SB/08 be expressly considered by the Examiner during the prosecution of this application, and that the document be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

The filing of this Information Disclosure Statement is not to be interpreted as a representation that the cited document is material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of the document herein be construed *per se* as a representation that such document is prior art. Moreover, Applicant understands the Examiner will make an independent evaluation of the cited document.

Application No.: 15/705,172

Docket No.: AVN-008CN41

This Information Disclosure Statement is filed within three months of the U.S. filing date (37 C.F.R. § 1.97(b)(1)). Applicant believes no fee is due with this statement.

Dated: September 26, 2017

Respectfully submitted,

Electronic signature: /Amy E. Mandragouras, Esq./  
Amy E. Mandragouras, Esq.  
Registration No.: 36,207  
NELSON MULLINS RILEY & SCARBOROUGH LLP  
One Post Office Square  
Boston, Massachusetts 02109-2127  
(617) 217-4626  
(617) 217-4699 (Fax)  
Attorney/Agent For Applicant

Doc code: IDS

32811

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2016. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number		15705172
	Filing Date		2017-09-14
	First Named Inventor		Stephen Donald WILTON
	Art Unit		1674
	Examiner Name	K. Chong	
	Attorney Docket Number		AVN-008CN41

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Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	
	1	20170009234	A1	2017-01-12	WILTON et al.		

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	K. Chong
Attorney Docket Number	AVN-008CN41

1	
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**EXAMINER SIGNATURE**

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

**\*EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	K. Chong
Attorney Docket Number	AVN-008CN41

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-26
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
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**Electronic Acknowledgement Receipt**

<b>EFS ID:</b>	30470917
<b>Application Number:</b>	15705172
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	2879
<b>Title of Invention:</b>	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF
<b>First Named Inventor/Applicant Name:</b>	Stephen Donald WILTON
<b>Customer Number:</b>	123147
<b>Filer:</b>	Amy E. Mandragouras/Anita Costa
<b>Filer Authorized By:</b>	Amy E. Mandragouras
<b>Attorney Docket Number:</b>	AVN-008CN41
<b>Receipt Date:</b>	26-SEP-2017
<b>Filing Date:</b>	14-SEP-2017
<b>Time Stamp:</b>	17:31:06
<b>Application Type:</b>	Utility under 35 USC 111(a)

**Payment information:**

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**File Listing:**

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	2017-00-26_IDSTRANS_AVN-008CN41_4837-0227-6945_v1.pdf	24722 a2f4b83aa8b4579bae0fe7b868490637ee44a3f7	no	2

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2	Information Disclosure Statement (IDS) Form (SB08)	SB08.pdf	1058268	no	4
			720550c02315856293e36d5f694fb7618ea 25b9a		

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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**From:** PAIR\_eOfficeAction@uspto.gov  
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**Subject:** Private PAIR Correspondence Notification for Customer Number 123147

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Application	Document	Mailroom Date	Attorney Docket No.
15705172	APP.FILE.REC	09/26/2017	AVN-008CN41

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/705,172	09/14/2017	Stephen Donald WILTON	AVN-008CN41	2879

123147	7590	10/05/2017
Nelson Mullins Riley & Scarborough LLP/Sarepta		
One Post Office Square		
Boston, MA 02109		

EXAMINER	
CHONG, KIMBERLY	

ART UNIT	PAPER NUMBER
1674	

NOTIFICATION DATE	DELIVERY MODE
10/05/2017	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com  
chris.schlauch@nelsonmullins.com  
ipqualityassuranceboston@nelsonmullins.com

Application No.  
15/705,172  
# 32819Applicant(s)  
WILTON ET AL.**Office Action Summary**Examiner  
KIMBERLY CHONGArt Unit  
1674AIA (First Inventor to File)  
Status  
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09/26/2017.  
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims\***

- 5) ☒ Claim(s) 2 and 3 is/are pending in the application.  
 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☒ Claim(s) 2 and 3 are subject to restriction and/or election requirement.

\* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).

**Application Papers**

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 09/14/2017 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

**Certified copies:**

- a) ☐ All b) ☐ Some\*\* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)  
 Paper No(s)/Mail Date 09/22/2017.
- 3) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_.
- 4) ☐ Other: \_\_\_\_.

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The present application is being examined under the pre-AIA first to invent provisions.

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Claims 2 and 3 are pending and currently under examination.

### ***Information Disclosure Statement***

The submission of the Information Disclosure Statements on 09/22/2017 is in compliance with 37 CFR 1.97. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 3 are rejected under pre-AIA 35 U.S.C. 103(a) as being obvious over van Ommen (WO2004/083432 cited on IDS filed 09/22/2017) and Koenig et al. (Nature 338, 509 - 511 06 April 1989 cited on IDS filed 09/22/2017).

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The claims are drawn to an antisense oligonucleotide of 20-31 bases comprising a base sequence 100% complementary to consecutive bases of exon 53 of the human dystrophin pre-mRNA, wherein the antisense oligonucleotide base sequence comprises at least 12 consecutive bases of SEQ ID NO: 195, wherein uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, and wherein the antisense induces exon 53 skipping. The claims are further drawn to a pharmaceutical composition comprising said antisense oligonucleotide.

van Ommen teach a genus of oligonucleotides 16-50 complementary to exon 53 and has identified an active range in the DMD gene and have shown two oligonucleotide h53AON1 and h53AON2 that cause skipping of exon 53 (see Table 2). van Ommen et al. teach the oligonucleotides can be complementary to the exon in the pre-mRNA. Thus given the sequence of the DMD gene has been identified, as demonstrated by Koenig et al., an oligonucleotide sequence complementary to that

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portion of the mRNA is exactly determined by the simple base pairing rules of DNA and RNA (G being complementary to C, and A being complementary to T (or U)).

vanOmmen et al. the oligonucleotide can have modifications such as morpholino phosphorodiamidate, peptide nucleic acid and locked nucleic acids, for example, and further teach the oligonucleotide comprises modified internucleoside linkages (see claim 12 and page 23). The oligonucleotide taught by van Ommen et al. encompasses both DNA and RNA nucleic acids as well as nucleic acids that are a combination of DNA and RNA as stated on page 9: lines 9-10 "Any oligonucleotide fulfilling the requirements of the invention may be used to induce exon skipping in the DMD gene." van Ommen et al. teach different nucleic acids may be used to generate the oligonucleotide (see page 9 line 30 - page 10). Thus oligonucleotides in which uracil bases are thymine bases are encompassed in the meaning of 'oligonucleotide' taught by van Ommen et al.

It would have been obvious to one of ordinary skill in the art to make an antisense oligonucleotide of 20-31 bases comprising at least 12 bases of SEQ ID No. 195. Given van Ommen et al. teach a genus of oligonucleotides of up to 50 nucleotides in length, one of skill in the art would have been motivated to use the sequence of h53AON1 to arrive at oligonucleotides of 20 nucleotides and having 12 nucleotides of SEQ ID No. 195 (which overlaps with 3 nucleotides of h53AON1). Because van Ommen et al. has identified exon 53 and shown oligonucleotides targeting this region can cause exon skipping and because the mRNA sequence containing the exon 53 was known in the prior art, as shown by Keonig et al., the combination of these teachings

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provides motivation to prepare obvious variants of h53AON1 to try and optimize the activity of the oligonucleotide to prepare the most effective therapeutic for treating DMD.

It would have been routine and a common strategy to try and enhance the oligonucleotide by identifying variants of that oligonucleotide that have a higher level of activity and a common and efficient strategy for doing so is to synthesize and test longer oligonucleotides containing within them the sequence known to have the desired activity.

Thus in the absence of evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP §



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717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit [www.uspto.gov/forms/](http://www.uspto.gov/forms/). The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-l.jsp>.

Claims 2 and 3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 8,455,636. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to antisense oligonucleotides having at least 17 consecutive bases of SEQ ID No. 193.

Claims 2 and 3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 8,232,384. Although the conflicting claims are not identical, they are not patentably

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distinct from each other because the instant claims and the claims of the patent are drawn to antisense oligonucleotides having at least 17 consecutive bases of SEQ ID No. 193.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

#### **706.07(a) Final Rejection, When Proper on Second Action [R-07.2015]**

Second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). Where information is submitted in an information disclosure statement during the period set forth in 37 CFR 1.97(c) with a fee, the examiner may use the information submitted, e.g., a printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP § 609.04(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong whose telephone number is 571-272-3111**. The examiner can normally be reached Monday thru Friday 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Ram Shukla at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Kimberly Chong/  
Primary Examiner  
Art Unit 1674

Doc code: IDS

# 32828

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2016. OMB 0651-0031

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number	15705172
	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	AVN-008CN41

U.S.PATENTS						<a href="#">Remove</a>
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	4458066		1984-07-03	Caruthers et al.	
	2	5034506		1991-07-23	Summerton et al.	
	3	5138045		1992-08-11	Cook et al.	
	4	5142047		1992-08-25	Summerton et al.	
	5	5149797		1992-09-22	Pederson et al.	
	6	5166315		1992-11-24	Summerton et al.	
	7	5185444		1993-02-09	Summerton et al.	
	8	5190931		1993-03-02	Inouye	

Application Number # 32829		15705172
Filing Date		2017-09-14
First Named Inventor	Stephen Donald WILTON	
Art Unit	1674	
Examiner Name	Not Yet Assigned	
Attorney Docket Number	AVN-008CN41	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

9	5217866		1993-06-08	Summerton et al.	
10	5506337		1996-04-09	Summerton et al.	
11	5521063		1996-05-28	Summerton et al.	
12	5627274		1997-05-06	Kole et al.	
13	5665593		1997-09-09	Kole et al.	
14	5698685		1997-12-16	Summerton et al.	
15	5801154		1998-09-01	Baracchini et al.	
16	5869252		1999-02-09	Bouma et al.	
17	5892023		1999-04-06	Pirotzky et al.	
18	5916808		1999-06-29	Kole et al.	
19	5976879		1999-11-02	Kole et al.	

Application Number # 32830	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

20	6153436		2000-11-28	Hermonat et al.	
21	6210892		2001-04-03	Bennett et al.	
22	6312900		2001-11-06	Dean et al.	
23	6391636		2002-05-21	Monia	
24	6451991		2002-09-17	Martin et al.	
25	6653466		2003-11-25	Matsuo	
26	6653467		2003-11-25	Matsuo et al.	
27	6656732		2003-12-02	Bennett et al.	
28	6727355		2004-04-27	Matsuo et al.	
29	6784291		2004-08-31	Iversen et al.	
30	6806084		2004-10-19	Debs et al.	

Application Number # 32831		15/05172
Filing Date		2017-09-14
First Named Inventor	Stephen Donald WILTON	
Art Unit	1674	
Examiner Name	Not Yet Assigned	
Attorney Docket Number	AVN-008CN41	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

31	7001761		2006-02-21	Xiao	
32	7070807		2006-07-04	Mixson	
33	7163695		2007-01-16	Mixson	
34	7250289		2007-07-31	Zhou	
35	7314750		2008-01-01	Zhou	
36	7468418		2008-12-23	Iversen et al.	
37	7534879		2009-05-19	van Deutekom	
38	7655785		2010-02-02	Bentwich	
39	7655788		2010-02-02	Khvorova et al.	
40	7807816		2010-10-05	Wilton et al.	
41	7902160		2011-03-08	Matsuo et al.	



Application Number # 32832		15/05172
Filing Date		2017-09-14
First Named Inventor	Stephen Donald WILTON	
Art Unit	1674	
Examiner Name	Not Yet Assigned	
Attorney Docket Number	AVN-008CN41	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

42	7960541		2011-06-14	Wilton et al.	
43	7973015		2011-07-05	van Ommen et al.	
44	8084601		2011-12-27	Popplewell et al.	
45	8232384		2012-07-31	Wilton et al.	
46	8324371		2012-12-04	Popplewell et al.	
47	8361979		2013-01-29	Aartsma-Rus et al.	
48	8436163		2013-05-07	Iversen et al.	
49	8450474		2013-05-28	Wilton et al.	
50	8455634		2013-06-04	Wilton et al.	
51	8455635		2013-06-04	Wilton et al.	
52	8455636		2013-06-04	Wilton et al.	

Application Number # 32833		15/05172
Filing Date		2017-09-14
First Named Inventor	Stephen Donald WILTON	
Art Unit	1674	
Examiner Name	Not Yet Assigned	
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Filing Date		2017-09-14
First Named Inventor	Stephen Donald WILTON	
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Examiner Name	Not Yet Assigned	
Attorney Docket Number	AVN-008CN41	

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Filing Date		2017-09-14
First Named Inventor	Stephen Donald WILTON	
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Examiner Name	Not Yet Assigned	
Attorney Docket Number	AVN-008CN41	

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First Named Inventor	Stephen Donald WILTON	
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Filing Date		2017-09-14
First Named Inventor	Stephen Donald WILTON	
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Attorney Docket Number	AVN-008CN41	

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15705172

Filing Date

2017-09-14

First Named Inventor

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Filing Date

2017-09-14

First Named Inventor

Stephen Donald WILTON

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First Named Inventor	Stephen Donald WILTON	
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Attorney Docket Number	AVN-008CN41	

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First Named Inventor	Stephen Donald WILTON	
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Examiner Name	Not Yet Assigned	
Attorney Docket Number	AVN-008CN41	

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Filing Date		2017-09-14
First Named Inventor	Stephen Donald WILTON	
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Examiner Name	Not Yet Assigned	
Attorney Docket Number	AVN-008CN41	

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Filing Date		2017-09-14
First Named Inventor	Stephen Donald WILTON	
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First Named Inventor	Stephen Donald WILTON	
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Attorney Docket Number	AVN-008CN41	

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Filing Date		2017-09-14
First Named Inventor	Stephen Donald WILTON	
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( Not for submission under 37 CFR 1.99)

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First Named Inventor

Stephen Donald WILTON

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2017-09-14

First Named Inventor

Stephen Donald WILTON

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AVN-008CN41

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First Named Inventor	Stephen Donald WILTON	
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32854	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32855	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32856	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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37	AON PS1959 Mass Spectrometry Data, Pages 5, Exhibit Number 1147 filed in Interferences 106,007 and 106,008 on February 16, 2015.
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39	AON PS1960 Mass Spectrometry Data, Pages 8, Exhibit Number 1148 filed in Interferences 106,007 and 106,008 on February 16, 2015.
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32857	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

43	AON PS1962 Mass Spectrometry Data, Pages 7, Exhibit Number 1150 filed in Interferences 106,007 and 106,008 on February 16, 2015.
44	AON PS1962 UPLC Data, Pages 2, Exhibit Number 1161 filed in Interferences 106,007 and 106,008 on February 16, 2015.
45	AON PS1963 Mass Spectrometry Data, Pages 10, Exhibit Number 1151 filed in Interferences 106,007 and 106,008 on February 16, 2015.
46	AON PS1963 UPLC Data, Pages 2, Exhibit Number 1162 filed in Interferences 106,007 and 106,008 on February 16, 2015.
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50	AON PS1965 UPLC Data, Pages 2, Exhibit Number 1164 filed in Interferences 106,007 and 106,008 on February 16, 2015.

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Examiner Signature	/KIMBERLY CHONG/ (10/01/2017)	Date Considered	10/01/2017
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Application Number # 32858	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number	15705172
	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	AVN-008CN41

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STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32861	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32862	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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15	International Preliminary Report on Patentability and Written Opinion for Application No. PCT/US2009/061960, 8 pages, dated April 26, 2011
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32863	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32864	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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43	King et al., "A Dictionary of Genetics," Oxford University Press, 4th Ed. (1990), Exhibit Number 1189 filed in Interferences 106,007 and 106,008 on February 17, 2015.
44	KOENIG, M. et al., "The Complete Sequence of Dystrophin Predicts a Rod-Shaped Cytoskeleton Protein," Cell, Vol. 53:219-228 (1988) (Exhibit Number 1010 filed in interferences 106008, 106007 on November 18, 2014)

**INFORMATION DISCLOSURE  
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Application Number # 32865	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

45	KOENIG, M. et al., "The Molecular Basis for Duchenne versus Becker Muscular Dystrophy: Correlation of Severity with Type of Deletion," Am. J. Hum. Genet., Vol. 45:498-506 (1989) (Exhibit Number 1011 filed in interferences 106008, 106007 on November 18, 2014)
46	Kohler M, et al., "Quality of life, physical disability and respiratory impairment in Duchenne muscular dystrophy," Am J Respir Crit Care Med 2005;172:1032-6.
47	KOLE et al. "Exon skipping therapy for Duchenne muscular dystrophy," Advanced Drug Delivery Reviews, vol. 87:104-107 (2015).
48	KOSHKIN, Alexei A. et al., "LNA (Locked Nucleic Acids): Synthesis of the Adenine, Cytosine, Guanine, 5-Methylcytosine, Thymine and Uracil Bicyclonucleoside Monomers, Oligomerisation, and Unprecedented Nucleic Acid Recognition," Tetrahedron, Vol. 54:3607-3630 (1998) (Exhibit Number 2007 filed in interferences 106008, 106013, 106007 on November 18, 2014)
49	Kurreck J., "Antisense Technologies: Improvement Through Novel Chemical Modifications", European Journal of Biochemistry, Vol.270(8):1628-1644 (2003)
50	Lab-on-a-Chip Data, Pages 28, Exhibit Number 1185 filed in Interferences 106,007 and 106,008 on February 16, 2015.

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Application Number # 32886	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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A certification statement is not submitted herewith.

**SIGNATURE**

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Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

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PTO/SB/08a (03-15)

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number	15705172
	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	AVN-008CN41

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32869	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

1	Sarepta Briefing Information for the April 25, 2016 Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee, Eteplirsen Briefing Document, NDA 206488, 186 pages.
2	Sarepta Presentation at Peripheral and Central Nervous System Drugs Advisory Committee, April 25, 2016, 133 pages
3	Sarepta Press Release, Sarepta Issues Statement on Advisory Committee Outcome for Use of Eteplirsen in the Treatment of Duchenne Muscular Dystrophy, April 25, 2016, 2 pages
4	Sarepta Therapeutics Press Release, dated January 12, 2015, Exhibit Number 1119 filed in interferences 106,007 and 106,008 on February 17, 2015.
5	Sarepta Therapeutics, Advisory Committee Briefing Materials: Available for Public Release, "Peripheral and Central Nervous System Drugs Advisory Committee," Eteplirsen Briefing Document Addendum, NDA 206488, pages 1-9, dated January 22, 2016.
6	Sarepta Therapeutics, Advisory Committee Briefing Materials: Available for Public Release, "Peripheral and Central Nervous System Drugs Advisory Committee," Eteplirsen Briefing Document, NDA 206488, pages 1-166, dated January 22, 2016.
7	Sarepta Therapeutics, Inc. News Release, "Sarepta Therapeutics Announces FDA Accelerated Approval of EXONDYS 51™ (eteplirsen) injection, an Exon Skipping Therapy to Treat Duchenne Muscular Dystrophy (DMD) Patients Amenable to Skipping Exon 51," September 19, 2016, 2 pages.
8	Sarepta, "AVI BioPharma Initiates Dosing in Phase 2 Study of Eteplirsen in Duchenne Muscular Dystrophy Patients," press release, 4 pages, dated August 15, 2011 (Exhibit Number 2082 filed in interferences 106008, 106013, 106007 on November 18, 2014)
9	Sarepta, "Sarepta Therapeutics Announces Eteplirsen Demonstrates Continued Stability on Walking Test through 120 Weeks in Phase Iib Study in Duchenne Muscular Dystrophy," press release, 3 pages, dated January 15, 2014 (Exhibit Number 2034 filed in interferences 106008, 106013, 106007 on November 18, 2014)
10	Sarepta, "Sarepta Therapeutics Reports Long-Term Outcomes through 144 Weeks from Phase Iib Study of Eteplirsen in Duchenne Muscular Dystrophy," press release, <a href="http://investorrelations.sarepta.com/phoenix.zhtml?c=64231&amp;p=irol-newsArticle&amp;id=1946426">http://investorrelations.sarepta.com/phoenix.zhtml?c=64231&amp;p=irol-newsArticle&amp;id=1946426</a> , 4 pages, dated July 10, 2014
11	Scully, Michele et al., "Review of Phase II and Phase III Clinical Trials for Duchenne Muscular Dystrophy", Expert Opinion on Orphan Drugs, Vol.1(1):33-46 (2013)

**INFORMATION DISCLOSURE  
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Application Number # 32870	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

12	Second Preliminary Amendment filed in US Application No. 13/550,210, 5 pages, dated January 3, 2013 (Exhibit Number 2062 filed in interferences 106008, 106013, 106007 on November 18, 2014)
13	Second Written Opinion for Application No. PCT/AU2010/001520, 7 pages, dated October 13, 2011
14	Semi Quantitative Lab-on-Chip Analysis of Second PCR Product, Pages 1, Exhibit Number 1183 filed in Interferences 106,007 and 106,008 on February 16, 2015.
15	Sequence Listing - Serial No. 13/550,210, as filed July 16, 2012 (9 pages), Exhibit Number 1205 filed in Interferences 106,007 and 106,008 on February 17, 2015.
16	Sequence of Exon 46 of Dystrophin Gene, 1 page
17	Sequence of Exon 51 of Dystrophin Gene, 1 page
18	Shabanpoor et al., "Bi-specific splice-switching PMO oligonucleotides conjugated via a single peptide active in a mouse model of Duchenne muscular dystrophy," Nucleic Acids Res., pp. 1-11 (December, 2014), Exhibit Number 1114 filed in interferences 106,007 and 106,008 on February 17, 2015.
19	SHAPIRO, Marvin B. et al., "RNA splice junctions of different classes of eukaryotes: sequence statistics and functional implications in gene expression," Nucleic Acids Research, Vol. 15(17):7155-7174 (1987)
20	SHERRATT, Tim G. et al., "Exon Skipping and Translation in Patients with Frameshift Deletions in the Dystrophin Gene," Am. J. Hum. Genet., Vol. 53:1007-1015 (1993)
21	SHIGA, Nobuyuki et al., "Disruption of the Splicing Enhancer Sequence within Exon 27 of the Dystrophin Gene by a Nonsense Mutation Induced Partial Skipping of the Exon and Is Responsible for Becker Muscular Dystrophy," J. Clin. Invest., Vol. 100(9):2204-2210 (1997)
22	SHIMIZU, Miho et al., "Oligo(2'-O-methyl)ribonucleotides Effective probes for duplex DNA," FEBS Letters, Vol. 302(2):155-158 (1992) (Exhibit Number 1035 filed in interferences 106008, 106007 on November 18, 2014)

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
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Application Number # 32871	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

23	Siemens Healthcare Diagnostics, Inc. v. Enzo Life Sciences, Inc., 2013 WL 4411227, *11 [Parallel cite: U.S.D.C., D. Mass., Civil No. 10-40124-FDS], Decided Aug. 14, 2013 (12 pages); [Cited as: 2013 WL 4411227], Exhibit Number 1210 filed in Interferences 106,007 and 106,008 on February 17, 2015.
24	SIERAKOWSKA, Halina et al., "Repair of thalassemic human beta-globin mRNA in mammalian cells by antisense oligonucleotides," Proc. Natl. Acad. Sci. USA, Vol. 93:12840-12844 (1996)
25	Sontheimer et al., "Metal ion catalysis during group II intron self-splicing: parallels with the spliceosome," Genes & Development, Vol. 13, pp. 1729-1741 (1999), Exhibit Number 1195 filed in Interferences 106,007 and 106,008 on February 17, 2015.
26	Sontheimer et al., "Three Novel Functional Variants of Human U5 Small Nuclear RNA," Vol. 12, No. 2, pp. 734-746 (Feb., 1992), Exhibit Number 1194 filed in Interferences 106,007 and 106,008 on February 17, 2015.
27	SONTHEIMER, Erik J. et al., "Metal ion catalysis during splicing of premessenger RNA," Nature, Vol. 388:801-805 (1997) (Exhibit Number 1036 filed in interferences 106008, 106007 on November 18, 2014)
28	SONTHEIMER, Erik J. et al., "The U5 and U6 Small Nuclear RNAs as Active Site Components of the Spliceosome," Science, Vol. 262:1989-1997 (1993) (Exhibit Number 1058 filed in interferences 106008, 106007 on November 18, 2014)
29	Standard Operating Procedure FPLC Desalting, Pages 6, Exhibit Number 1144 filed in Interferences 106,007 and 106,008 on February 16, 2015.
30	Stanton, Robert et al., "Chemical Modification Study of Antisense Gapmers", Nucleic Acid Therapeutics, Vol. 22(5): 344-359 (2012)
31	Statement On A Nonproprietary Name Adopted By the USAN Council, ETEPLIRSEN, Chemical Structure, 2010, pages 1-5.
32	STEIN, CA, "Delivery of antisense oligonucleotides to cells: a consideration of some of the barriers," Monographic supplement series: Oligos & Peptides - Chimica Oggi - Chemistry Today, Vol. 32(2):4-7 (2014) (Exhibit Number 2022 filed in interferences 106008, 106013, 106007 on November 18, 2014)
33	STEIN, Cy A. et al., "Therapeutic Oligonucleotides: The Road Not Taken," Clin. Cancer Res., Vol. 17(20):6369-6372 (2011) (Exhibit Number 2026 filed in interferences 106008, 106013, 106007 on November 18, 2014)



**INFORMATION DISCLOSURE  
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Application Number # 32872	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

34	STEIN, David et al., "A Specificity Comparison of Four Antisense Types: Morpholino, 2'-O-Methyl RNA, DNA, and PHosphorothioate DNA," Antisense & Nucleic Acid Drug Development, Vol. 7:151-157 (1997)
35	Strober JB, "Therapeutics in Duchenne muscular dystrophy," NeuroRX 2006; 3:225-34.
36	Summary of Professional Experience (Dr. Erik J. Sontheimer), Pages 4, Exhibit Number 1223 filed in Interferences 106,007 and 106,008 on February 17, 2015.
37	SUMMERTON, James et al., "Morpholino and Phosphorothioate Antisense Oligomers Compared in Cell-Free and In-Cell Systems," Antisense & Nucleic Acid Drug Development, Vol. 7:63-70 (1997)
38	SUMMERTON, James et al., "Morpholino Antisense Oligomers: Design, Preparation, and Properties," Antisense & Nucleic Acid Drug Development, Vol. 7:187-195 (1997)
39	SUMMERTON, James, "Morpholino antisense oligomers: the case for an RNase H-independent structural type," Biochimica et Biophysica Acta, Vol. 1489:141-158 (1999) (Exhibit Number 1038 filed in interferences 106008, 106013, 106007 on November 18, 2014)
40	Supplementary European Search Report for Application No. 10829367.1, 8 pages, dated May 22, 2013
41	Suter et al., "Double-target antisense U7 snRNAs promote efficient skipping of an aberrant exon in three human Beta-thalassemic mutations," 8:13 HUMAN MOLECULAR GENETICS 2415-2423 (1999) (Exhibit Number 1083 filed in interferences 106008, 106007 on December 23, 2014)
42	T HOEN, Peter A.C. et al., "Generation and Characterization of Transgenic Mice with the Full-length Human DMD Gene," The Journal of Biological Chemistry, Vol. 283(9):5899-5907 (2008) Exhibit Number 2030 filed in interferences 106008, 106013, 106007 on November 18, 2014)
43	Table 1: Primer and Product Details for Exon 51 and 53 Reports on AONs of 20 to 50 Nucleotides dd 07 JAN 2015, Pages 1, Exhibit Number 1177 filed in Interferences 106,007 and 106,008 on February 16, 2015.
44	Takeshima et al., "Oligonucleotides against a splicing enhancer sequence led to dystrophin production in muscle cells from a Duchenne muscular dystrophy patient," Brain & Dev., Vol. 23, pp. 788-790 (2001), Exhibit Number 1196 filed in Interferences 106,007 and 106,008 on February 17, 2015.

Application Number # 32873	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
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45	TAKESHIMA, Yasuhiro et al., "Modulation of In Vitro Splicing of the Upstream Intron by Modifying an Intra-Exon Sequence Which Is Deleted from the Dystrophin Gene in Dystrophin Kobe," J. Clin. Invest., Vol. 95:515-520 (1995)
46	TANAKA, Kenji et al., "Polypurine Sequences within a Downstream Exon Function as a Splicing Enhancer," Molecular and Cellular Biology, Vol. 14(2):1347-1354 (1994)
47	Telios Pharms., Inc. v. Merck KgaA, No. 96-1307, 1998 WL 35272018 (S.D. Cal. Nov. 18, 1998), 11 pages (Exhibit Number 2153 filed in interference 106013 on October 29, 2015)
48	THANH, Le Htiet et al., "Characterization of Revertant Muscle Fibers in Duchenne Muscular Dystrophy, Using Exon-Specific Monoclonal Antibodies against Dystrophin," Am. J. Hum. Genet., Vol. 56:725-731 (1995)
49	The Regents of the University of California v. Dako North America, Inc., U.S.D.C., N.D. California, No. C05-03955 MHP, April 22, 2009 (2009 WL 1083446 (N.D.Cal.), Exhibit Number 1206 filed in Interferences 106,007 and 106,008 on February 17, 2015.
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First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Doc code: IDS

# 32876

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number	15705172
	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	AVN-008CN41

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STATEMENT BY APPLICANT**  
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Application Number # 32877	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

1	Excerpts of SEC Form 8-K, dated November 23 2014, for BioMarin Pharmaceutical Inc., (University of Western Australia Exhibit 2129, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-9).
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3	Exon 51 Internal Sequence Schematic, Pages 1, Exhibit Number 1224 filed in Interferences 106,007 and 106,008 on February 17, 2015.
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Application Number # 32878	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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13	FEENER, C. et al., "Alternative splicing of human dystrophin mRNA generates isoforms at the carboxy terminus," Nature, vol. 338:509 - 511 (1989).
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15	File Excerpt from AZL U.S. Patent Application 11/233,495: Claims examined in Non-Final Office Action, dated December 1, 2008 (Exhibit Number 1079 filed in interferences 106008, 106007 on December 23, 2014)
16	File Excerpt from AZL U.S. Patent Application 11/233,495: Final Office Action dated August 31, 2010 (Exhibit Number 1086 filed in interferences 106008, 106007 on December 23, 2014)
17	File Excerpt from U.S. Patent Application 11/233,495: Non-Final Office Action dated December 1, 2008 and Final Office Action dated June 25, 2009 (Exhibit Number 1078 filed in interferences 106008, 106007 on December 23, 2014)
18	File Excerpt from U.S. Patent Application No. 12/198,007: AZL's Preliminary Amendment and Response, as-filed November 7, 2008 (Exhibit Number 1075 filed in interferences 106008, 106007 on December 23, 2014)
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21	File Excerpts from U.S. Patent Application No. 11/233,495: Response to Non- Final Office Action, as filed July 26, 2011 (14 pages), Exhibit Number 1222 filed in Interferences 106,007 and 106,008 on February 17, 2015.
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
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Application Number # 32879	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32880	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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41	GENNARO, Alfonso R., (ed.), Remington's Pharmaceutical Sciences, 18th Edition, Mack Publishing, Co., Easton PA, 2020 pages (1990)
42	GILES, Richard V. et al., "Antisense Morpholino Oligonucleotide Analog Induces Missplicing of C-myc mRNA," Antisense & Nucleic Acid Drug Development, Vol. 9:213-220 (1999)
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32881	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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Examiner Signature	/KIMBERLY CHONG/ (10/01/2017)	Date Considered	10/01/2017
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Application Number # 32882	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
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PTO/SB/08a (03-15)

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	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	AVN-008CN41

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STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32885	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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3	Morcos, Paul A., "Gene switching: analyzing a broad range of mutations using steric block antisense oligonucleotides," Methods in Enzymology, Vol. 313:174-189 (1999)
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32886	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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13	Oligonucleotide Cleavage and Deprotection Laboratory Notebook Entry, Pages 1, Exhibit Number 1138 filed in Interferences 106,007 and 106,008 on February 16, 2015.
14	Oligonucleotide diagrams, 5 pages (Exhibit Number 1053 filed in interferences 106008, 106007 on November 18, 2014)
15	Partial European Search Report for Application No. 10004274.6, 6 pages, dated October 2, 2012
16	Partial European Search Report for Application No. 12162995.0, 6 pages, dated October 2, 2012
17	Patentee's Response to European Patent Application No. 05076770.6, dated July 28, 2006, 4 pages
18	Patrick O. Brown and Tidear D. Shalon v. Stephen P.A. Fodor, Dennis W. Solas and William J. Dower: Interference Merits Panel, Interference No. 104,358, 24 pages, dated August 9, 1999 (Exhibit Number 2113 filed in interferences 106008, 106013, 106007 on November 18, 2014)
19	PCT Application as-filed for application No. PCT/NL03/00214, 64 pages, dated September 21, 2005 (Exhibit Number 2042 filed in interferences 106008, 106013, 106007 on November 18, 2014)
20	PD-10 Desalting Columns, Pages 12, Exhibit Number 1141 filed in Interferences 106,007 and 106,008 on February 16, 2015.
21	Popplewell, et al., Design of Phosphorodiamidate Morpholino Oligomers (PMOs) For the Induction of Exon Skipping of the Human DMD Gene, DSGT Poster, 2008, 1 page.
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Application Number # 32887	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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28	Pramono, "Induction of Exon Skipping of the Dystrophin Transcript in Lymphoblastoid Cells by Transfecting an Antisense Oligodeoxynucleotide Complementary to an Exon Recognition Sequence," Biochem. and Biophys. Res. Comm., Vol. 226, pp. 445-449 (1996), Exhibit Number 1192 filed in Interferences 106,007 and 106,008 on February 17, 2015.
29	Preliminary Amendment for Application No. 12/976,381, 4 pages, dated December 22, 2010 (Exhibit Number 2066 filed in interferences 106008, 106013, 106007 on November 18, 2014)
30	Preliminary Amendment for Application No. 12/198,007, 3 pages, dated November 7, 2008 (Exhibit Number 2067 filed in interferences 106008, 106013, 106007 on November 18, 2014)
31	Prescribing Information for EXONDYS 51 (eteplirsen) Injection, dated 09/2016, 10 pages
32	Program Schedule for The Tenth Annual Meeting of the RNA Society, held at the Banff Centre for Conferences, in Banff, Alberta, Canada, from May 24-29, 2005, (University of Western Australia Exhibit 2136, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).
33	Proliferation and Differentiation of Myoblast Cultures, Pages 2, Exhibit Number 1169 filed in Interferences 106,007 and 106,008 on February 16, 2015.



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Attorney Docket Number	AVN-008CN41

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35	Prosensa, "GSK and Prosensa Announce Primary Endpoint Not Met in Phase III Study of Drisapersen in Patients With Duchenne Muscular Dystrophy," press release, 4 pages, dated September 20, 2013 (Exhibit Number 2039 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
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40	Reply to EPO Communication dated June 26, 2014 in European Application Serial No. 13160338, (University of Western Australia Exhibit 2145, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).
41	Reply to EPO Communication dated October 21, 2014 in European Application Serial No. 12198517, (University of Western Australia Exhibit 2148, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-7).
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43	Response to Office Action and Amendments to the Claims for Application No. 13/550,210, 10 pages, dated May 12, 2014 (Exhibit Number 2064 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
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Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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46	ROBERTS, Roland G. et al., "Exon Structure of the Human Dystrophin Gene," Genomics, Vol. 16:536-538 (1993)
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49	Saito, T. et al., "First-in-Human Study of NS-065/NCNP-01; the Morpholino Based Antisense Oligonucleotide for Exon 53 Skipping in Duchenne Muscular Dystrophy," ASGCT meeting , May 13, 2015, Abstract [136] 1 page.
50	Saito, T. et al., "First-in-Human Study of NS-065/NCNP-01; the Morpholino Based Antisense Oligonucleotide for Exon 53 Skipping in Duchenne Muscular Dystrophy," ASGCT meeting , May 13, 2015, pages 1-11.

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Art Unit	1674
Examiner Name	Not Yet Assigned
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Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
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	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
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	1	2011/045747	WO	A1	2011-04-21	Universita Delgi Studi Di Ferrara		
	2	2011/057350	WO	A1	2011-05-19	The University of Western Australia		
	3	2011/143008	WO	A1	2011-11-17	The Charlotte-Mecklenburg Hospital Authority D/B/A		

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Filing Date		2017-09-14
First Named Inventor	Stephen Donald WILTON	
Art Unit	1674	
Examiner Name	Not Yet Assigned	
Attorney Docket Number	AVN-008CN41	

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4	2012/001941	WO	A1	2012-01-05	Hagiwara, Masatoshi et al.	<input checked="" type="checkbox"/>
5	2012/029986	WO	A1	2012-03-08	Nippon Shinyaku Co., Ltd. et al.	<input type="checkbox"/>
6	2012/043730	WO	A1	2012-04-05	Nippon Shinyaku Co., Ltd.	<input checked="" type="checkbox"/>
7	2012/109296	WO	A1	2012-08-16	The Charlotte-Mecklenburg Hospital Authority D/B/A	<input type="checkbox"/>
8	2012/150960	WO	A1	2012-11-08	Avi Biopharma, Inc	<input type="checkbox"/>
9	2013/033407	WO	A2	2013-03-07	The Regents of the University of California	<input type="checkbox"/>
10	2013/053928	WO	A1	2013-04-18	Association Institut De Myologie et al.	<input type="checkbox"/>
11	2013/100190	WO	A1	2013-07-04	Nippon Shinyaku Co., Ltd. et al.	<input checked="" type="checkbox"/>
12	2013/112053	WO	A1	2013-08-01	Prosensa Technologies B.V.	<input type="checkbox"/>
13	2013/142087	WO	A1	2013-09-26	Sarepta Therapeutics, Inc	<input type="checkbox"/>
14	2014/007620	WO	A2	2014-01-09	Prosensa Technologies B.V.	<input type="checkbox"/>



Application Number # 32894		15/05172
Filing Date		2017-09-14
First Named Inventor	Stephen Donald WILTON	
Art Unit	1674	
Examiner Name	Not Yet Assigned	
Attorney Docket Number	AVN-008CN41	

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15	2014/100714	WO	A1	2014-06-26	Sarepta Therapeutics, Inc	<input type="checkbox"/>
16	2014/144978	WO	A2	2014-09-18	Sarepta Therapeutics, Inc	<input type="checkbox"/>
17	2014/153220	WO	A2	2014-09-25	Sarepta Therapeutics, Inc	<input type="checkbox"/>
18	2014/153240	WO	A2	2014-09-25	Sarepta Therapeutics, Inc	<input type="checkbox"/>
19	2014/172669	WO	A1	2014-10-23	Res Inst At Nationwide Children S Hospital	<input type="checkbox"/>
20	2017/059131	WO	A1	2017-04-06	Sarepta Therapeutics, Inc	<input type="checkbox"/>
21	93/20227	WO	A1	1993-10-14	Abbott Laboratories	<input type="checkbox"/>
22	94/02595	WO	A1	1994-02-03	Ribozyme Pharmaceuticals, Inc.	<input type="checkbox"/>
23	94/26887	WO	A1	1994-11-24	The University of North Carolina at Chapel Hill	<input type="checkbox"/>
24	96/10391	WO	A1	1996-04-11	The University of British Columbia	<input type="checkbox"/>
25	96/10392	WO	A1	1996-04-11	The University of British Columbia	<input type="checkbox"/>

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Application Number # 32895	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

26	97/30067	WO	A1	1997-08-21	sis Pharmaceuticals, Inc.	<input type="checkbox"/>
27	97/34638	WO	A1	1997-09-25	The Regents of the University of California	<input type="checkbox"/>

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1	Classification Excerpts from USPC System, 21 pages, (Academisch Ziekenhuis Leiden Exhibit 1234, filed May 5, 2015 in Interference 106007 and 106008).	
	2	COLLINS, C.A. et al., "Duchenne's muscular dystrophy: animal models used to investigate pathogenesis and develop therapeutic strategies," Int. J. Exp. Pathol., Vol. 84(4):165-172 (2003)	
	3	Confirmation of Dystrophin Exon 48 to 50 Deletion in Cell Line 8036 Laboratory Notebook Entry, Pages 3, Exhibit Number 1167 filed in Interferences 106,007 and 106,008 on February 16, 2015.	
	4	Confirmation of Dystrophin Exon 52 Deletion in Cell Line R1809 Laboratory; Notebook Entry, Pages 3, Exhibit Number 1168 filed in Interferences 106,007 and 106,008 on February 16, 2015.	
	5	Confirmatory Study of Eteplirsen in DMD Patients, An Open-Label, Multi-Center, 48-Week Study With a Concurrent Untreated Control Arm to Evaluate the Efficacy and Safety of Eteplirsen in Duchenne Muscular Dystrophy ,Clinical Trials.gov, Clinical Trial Identifier NCT02255552, October 1, 2014, 3 pages	
	6	Coolidge v. Efendic, 2008 WL 2080735, Int. No. 105,457 (BPAI May 16, 2008), 42 pages, (Academisch Ziekenhuis Leiden Exhibit 1235, filed May 5, 2015 in Interference 106007 and 106008).	
	7	COREY, David R. et al., "Morpholino antisense oligonucleotides: tools for investigating vertebrate development," Genome Biology, Vol. 2(5):1015.1 - 1015.3 (2001) (Exhibit Number 1026 filed in interferences 106008, 106007 on November 18, 2014)	



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Application Number # 32896	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

8	Corrected Priority Statement filed by UWA in Int. No. 106,008 (as PN 219), Pages 5, Exhibit Number 1002 filed in Interference 106,013 on February 17, 2015.
9	Cortes et al., "Mutations in the conserved loop of human U5 snRNA generate use of novel cryptic 5' splice sites in vivo," EMBO J., Vol. 12, No. 13, pp. 5181-5189 (1993), Exhibit Number 1187 filed in Interferences 106,007 and 106,008 on February 17, 2015.
10	CROOKE, Stanley T., Antisense Drug Technology, Principles, Strategies, and Applications, Marcel Dekker, Inc., New York, Chapters 15 and 16, pages 375-389, 391-469 (2001) (Exhibit Number 2075 filed in interferences 106008, 106013, 106007 on November 18, 2014)
11	Curriculum Vitae of Judith van Deutekom, Pages 6, Exhibit Number 1126 filed in interferences 106,007 and 106,008 on February 17, 2015.
12	Curriculum Vitae, Erik Joseph Sontheimer, 18 pages, dated September 29, 2014 (Exhibit Number 1013 filed in interferences 106008, 106007 on November 18, 2014)
13	CV, Professor Matthew J.A. Wood, 3 pages (Exhibit Number 2003 filed in interferences 106008, 106007 on November 18, 2014)
14	DAVIS, Richard J. et al., "Fusion of PAX7 to FKHR by the Variant t(1;13)(p36;q14) Translocation in Alveolar Rhabdomyosarcoma," Cancer Research, Vol. 54:2869-2872 (1994) (Exhibit Number 1027 filed in interferences 106008, 106007 on November 18, 2014)
15	DE ANGELIS, Fernanda Gabriella et al., "Chimeric snRNA molecules carrying antisense sequences against the splice junctions of exon 51 of the dystrophic pre-mRNA induce exon skipping and restoration of a dystrophin synthesis in 48-50 DMD cells," PNAS, Vol. 99(14):9456-9461 (2002)
16	Decision on Appeal, Ex Parte Martin Gleave and Hideaki Miyake, Appeal No. 2005-2447, Appl. No. 09/619,908 (January 31, 2006) (2009 WL 6927761 (Bd.Pat.App.& Interf.), Pages 12, Exhibit Number 1207 filed in Interferences 106,007 and 106,008 on February 17, 2015.
17	Decision on Request for ReHearing, Ex Parte Roderick John Scott, Appeal No. 2008-004077, Appl. No. 10/058,825 (January 6, 2010) (2010 WL 191079 (Bd.Pat.App. & Interf.), Pages 21, Exhibit Number 1208 filed in Interferences 106,007 and 106,008 on February 17, 2015.
18	Declaration of Judith C.T. van Deutekom Under 37 C.F.R. §1.132, filed on January 27, 2012, in U.S. Patent Reexamination Control No 90/011,320, regarding U.S. Patent No. 7,534,879, (University of Western Australia Exhibit 2133, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-10).

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Application Number # 32897	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

19	Declaration of Judith van Deutekom, Pages 45, Exhibit Number 1125 filed in interferences 106,007 and 106,008 on February 17, 2015.
20	DELLORUSSO, Christiana et al., "Functional correction of adult mdx mouse muscle using gutted adenoviral vectors expressing full-length dystrophin," PNAS, Vol. 99(20):12979-12984 (2002)
21	Deposition Transcript of Erik J. Sontheimer, Ph.D. of January 21, 2015 (99 pages), Exhibit Number 1215 filed in Interferences 106,007 and 106,008 on February 17, 2015.
22	Deposition Transcript of Matthew J. A. Wood, M.D., D. Phil., January 22, 2015, including Errata Sheet, Pages 198, Exhibit Number 1007 filed in Interference 106,013 on February 17, 2015.
23	Deposition Transcript of Matthew J. A. Wood, M.D., D. Phil., Pages 196, Exhibit Number 1122 filed in interferences 106,007 and 106,008 on February 17, 2015.
24	Desalting of Oligonucleotides, Pages 2, Exhibit Number 1132 filed in Interferences 106,007 and 106,008 on February 17, 2015.
25	DIRKSEN, Wessel P. et al., "Mapping the SF2/ASF Binding Sites in the Bovine Growth Hormone Exonic Splicing Enhancer," The Journal of Biological Chemistry, Vol. 275(37):29170-29177 (2000)
26	DOMINSKI, Zbigniew et al., "Identification and Characterization by Antisense Oligonucleotides of Exon and Intron Sequences Required for Splicing," Molecular and Cellular Biology, Vol. 14(11):7445-7454 (1994)
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28	DORAN, Philip et al., "Proteomic profiling of antisense-induced exon skipping reveals reversal of pathobiochemical abnormalities in dystrophic mdx diaphragm," Proteomics, Vol. 9:671-685, DOI 10.1002/pmic.200800441 (2009)
29	DOUGLAS, Andrew G.L. et al., "Splicing therapy for neuromuscular disease," Molecular and Cellular Neuroscience, Vol. 56:169-185 (2013) (Exhibit Number 2005 filed in interferences 106008, 106013, 106007 on November 18, 2014)

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32898	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

30	Doyle, Donald F., et al. (2001) "Inhibition of Gene Expression Inside Cells by PeptideNucleic Acids: Effect of mRNA Target Sequence, Mismatched Bases, and PNA Length," Biochemistry 40:53-64, (Exhibit Number 2123 filed in Interferences 106,007 and 106,008 on February 17, 2015.
31	Dr. Wood Errata Sheet - 22 Jan 2015, Pages 2, Exhibit Number 1227 filed in Interferences 106,007 and 106,008 on February 17, 2015.
32	DUNCKLEY, Matthew G. et al., "Modification of splicing in the dystrophin gene in cultured Mdx muscle cells by antisense oligoribonucleotides," Human Molecular Genetics, Vol. 5(1):1083-1090 (1995)
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34	ECKSTEIN, F., "Nucleoside Phosphorothioates," Ann. Rev. Biochem., Vol. 54:367-402 (1985) (Exhibit Number 1028 filed in interferences 106008, 106007 on November 18, 2014)
35	ELAYADI, Anissa N. et al., "Application of PNA and LNA oligomers to chemotherapy," Current Opinion in Investigational Drugs, Vol. 2(4):558-561 (2001)
36	Email from Danny Huntington to Interference Trial Section, dated September 21, 2014, Pages 2, Exhibit Number 3001 filed in Interference 106,007, 106,008, and 106,013 on September 26, 2014.
37	Email From Sharon Crane to Interference Trial Section, dated November 13, 2014, Pages 2, Exhibit Number 3002 filed in Interference 106,007, 106,008, and 106,013 on dated November 14, 2014.
38	Emery, A.E. H., "Population frequencies of inherited neuromuscular diseases - a world survey," Neuromuscul Disord 1991;1:19-29.
39	Errata sheet for the January 22, 2015 deposition of Matthew J. A. Wood, M.D., D. PHIL., 2 pages, (Exhibit Number 2128 filed in interferences 106,007 and 106,008 on February 17, 2015.
40	Errata sheet for the March 12, 2015 deposition of Erik J. Sontheimer, Ph.D., (University of Western Australia Exhibit 2149, filed April 3, 2015 in Interferences 106007, 106008, and 106013, page 1).

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32899	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

41	Errata to the Sarepta Briefing Information for the April 25, 2016 Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee, Eteplirsan Errata Document, NDA 206488, 5 pages.
42	ERRINGTON, Stephen J. et al., "Target selection for antisense oligonucleotide induced exon skipping in the dystrophin gene," The Journal of Gene Medicine, Vol. 5:518-527 (2003)
43	European Office Action for Application No. 09752572.9, 5 pages, dated February 29, 2012
44	European Response, Application No. 10004274.6, 7 pages, dated November 5, 2013 (Exhibit Number 1060 filed in Interferences 106008, 106007 on November 18, 2014)
45	European Response, Application No. 12198517.0, 7 pages, dated October 21, 2014 (Exhibit Number 2084 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
46	European Search Report for Application No. 10004274.6, 12 pages, dated January 2, 2013
47	European Search Report, EP15168694.6, dated July 23, 2015, pages 1-8.
48	Excerpts from Prosecution History of Application No. 13/741,150: Notice of Allowance dated March 16, 2015; List of References cited by Applicant and Considered by Examiner; Notice of Allowance and Fees due dated September 18, 2014; Amendment in Response to Non-Final Office Action dated July 11, 2014, (Academisch Ziekenhuis Leiden Exhibit 1229, filed April 3, 2015 in Interference 106007 and 106008, pages 1-133).
49	Excerpts from Prosecution History of Application No. 13/826,880: Notice of Allowance dated January 26, 2015 and Amendment in Response to Non-Final Office Action dated October 15, 2014, (Academisch Ziekenhuis Leiden Exhibit 1228, filed April 3, 2015 in Interference 106007 and 106008, pages 1-16).
50	Excerpts from Yeo (Ed.), "Systems Biology of RNA Binding Proteins," Adv. Exp. Med. Biol., Chapter 9, 56 pages (2014), (Academisch Ziekenhuis Leiden Exhibit 1232, filed April 3, 2015 in Interference 106007 and 106008, pages 1-56).

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**INFORMATION DISCLOSURE  
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Application Number # 32900	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

**EXAMINER SIGNATURE**

Examiner Signature	/KIMBERLY CHONG/ (10/01/2017)	Date Considered	10/01/2017
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Application Number # 32901	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number	15705172
	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	AVN-008CN41

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32904	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

1	Laboratory Notebook Entry (Exon 51 Experiments): RT-PCR Analysis of 8036 Cells, Pages 2, Exhibit Number 1179 filed in Interferences 106,007 and 106,008 on February 16, 2015.
2	Laboratory Notebook Entry (Exon 51 Experiments): RT-PCR Analysis of KM155.C25 Cells, Pages 2, Exhibit Number 1178 filed in Interferences 106,007 and 106,008 on February 16, 2015.
3	Laboratory Notebook Entry (Exon 51 Experiments): Transfection of 8036 Cells, Pages 1, Exhibit Number 1172 filed in Interferences 106,007 and 106,008 on February 16, 2015.
4	Laboratory Notebook Entry (Exon 51 Experiments): Transfection of KM155.C25 Cells, Pages 1, Exhibit Number 1171 filed in Interferences 106,007 and 106,008 on February 16, 2015.
5	Laboratory Notebook Entry (Exon 53 Experiments): RT-PCR Analysis of KM155.C25 Cells, Pages 2, Exhibit Number 1180 filed in Interferences 106,007 and 106,008 on February 16, 2015.
6	Laboratory Notebook Entry (Exon 53 Experiments): RT-PCR Analysis of R1809 Cells, Pages 2, Exhibit Number 1181 filed in Interferences 106,007 and 106,008 on February 16, 2015.
7	Laboratory Notebook Entry (Exon 53 Experiments): Transfection of KM155.C25 Cells, Pages 1, Exhibit Number 1173 filed in Interferences 106,007 and 106,008 on February 16, 2015.
8	Laboratory Notebook Entry (Exon 53 Experiments): Transfection of R1809 Cells, Pages 1, Exhibit Number 1174 filed in Interferences 106,007 and 106,008 on February 16, 2015.
9	Claims from US Application No. 11/233,495, 6 pages, dated September 21, 2005 (Exhibit Number 2068 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
10	Laboratory Notebook Entry: General RNA recovery, Pages 2, Exhibit Number 1176 filed in Interferences 106,007 and 106,008 on February 16, 2015.
11	Laboratory Notebook Entry: Lab-on-a-Chip Analysis, Pages 3, Exhibit Number 1184 filed in Interferences 106,007 and 106,008 on February 16, 2015.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32905	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

12	Larsen et al., "Antisense properties of peptide nucleic acid," Biochim. Et Biophys. Acta, Vol. 1489, pp. 159-166 (1999), Exhibit Number 1190 filed in Interferences 106,007 and 106,008 on February 17, 2015.
13	Letter from the FDA to Sarepta Therapeutics, Inc., Re: ACCELERATED APPROVAL for the use of Exondys 51 (eteplirsen), FDA Reference ID: 3987286, dated September 19, 2016, 11 pages.
14	Letter to the U.S. Food and Drug Administration, (Dr. Billy Dunn, M.D. Director Division of Neurology Products, Office of Drug Evaluation 1, Center for Drug Evaluation and Research), for The Peripheral and Central Nervous System Advisory Committee Meeting (AdComm) supporting approval of eteplirsen, dated February 24, 2016, 4 pages.
15	Letter to the U.S. Food and Drug Administration, (Dr. Janet Woodcock, M.D. Director, CDER), from The Congress of The United States regarding Duchenne muscular dystrophy, dated February 17, 2016, 7 pages.
16	List of Publications for Matthew J. A. Wood, M.D., D. PHIL., 11 pages, (Exhibit Number 2124 filed in interferences 106,007 and 106,008 on February 17, 2015.
17	LIU, Hong-Xiang et al., "Identification of functional exonic splicing enhancer motifs recognized by individual SR proteins," Genes & Development, Vol. 12:1998-2012 (1998)
18	Lu et al, "Massive Idiosyncratic Exon Skipping Corrects the Nonsense Mutation in Dystrophic Mouse Muscle and Produces Functional Revertant Fibers by Clonal Expansion," THE JOURNAL OF CELL BIOLOGY, Vol. 148(5): 985-995, March 6, 2000 ("Lu et al.") (Exhibit Number 1082 filed in interferences 106008, 106007 on December 23, 2014)
19	LU, Qi Long et al., "Functional amounts of dystrophin produced by skipping the mutated exon in the mdx dystrophic mouse," Nature Medicine, Vol. 9(8):1009-1014 (2003)
20	LU, Qi-long et al., "What Can We Learn From Clinical Trials of Exon Skipping for DMD?" Molecular Therapy - Nucleic Acids, Vol. 3:e152, doi:10.1038/mtna.2014.6, 4 pages (2014)
21	Lyophilisation of Oligonucleotides, Pages 2, Exhibit Number 1133 filed in Interferences 106,007 and 106,008 on February 17, 2015.
22	MANN, Christopher J. et al., "Antisense-induced exon skipping and synthesis of dystrophin in the mdx mouse," PNAS, Vol. 98(1):42-47 (2001)

Application Number # 32906	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

23	MANN, Christopher J. et al., "Improved antisense oligonucleotide induced exon skipping in the mdx mouse model of muscular dystrophy," The Journal of Gene Medicine, Vol. 4:644-654 (2002)
24	MANNINO, Raphael J. et al., "Liposome Mediated Gene Transfer," BioTechniques, Vol. 6(7):682-690 (1988)
25	Manual of Patent Examining Procedure 2308.02 (6th ed., rev. 3, July 1997), (University of Western Australia Exhibit 2143, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-2).
26	Manzur A, et al., "Glucocorticoid corticosteroids for Duchenne muscular dystrophy," Cochrane Database Syst Rev. 2004;(2):CD003725.
27	MARSHALL, N.B. et al., "Arginine-rich cell-penetrating peptides facilitate delivery of antisense oligomers into murine leukocytes and alter pre-mRNA splicing," Journal of Immunological Methods, Vol. 325:114-126 (2007)
28	Mathews et al., "Expanded Sequence Dependence of Thermodynamic Parameters Improves Prediction of RNA Secondary Structure," J. Mol. Biol. 288:911-940 (1999), (University of Western Australia Exhibit 2131, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-31).
29	Mathews et al., "Expanded Sequence Dependence of Thermodynamic Parameters Improves Prediction of RNA Secondary Structure," J. Mol. Biol., Vol. 288, pp. 911-940 (1999), Exhibit Number 1212 filed in Interferences 106,007 and 106,008 on February 17, 2015.
30	MATSUO, Masafumi et al., "Exon Skipping during Splicing of Dystrophin mRNA Precursor due to an Intraexon Deletion in the Dystrophin Gene of Duchenne Muscular Dystrophy Kobe," J. Clin. Invest., Vol. 87:2127-2131 (1991)
31	MATSUO, Masafumi et al., "Treatment of Duchenne Muscular Dystrophy with Oligonucleotides against an Exonic Splicing Enhancer Sequence," Basic Appl. Myol., Vol. 13(6):281-285 (2003)
32	MATSUO, Masafumi, "Duchenne and Becker Muscular Dystrophy: From Gene Diagnosis to Molecular Therapy," JUBMB Life, Vol. 53:147-152 (2002)
33	MATSUO, Masafumi, "Duchenne/Becker muscular dystrophy: from molecular diagnosis to gene therapy," Brain & Development, Vol. 18:167-172 (1996)

Application Number # 32907	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

34	MATTEUCCI, Mark, "Structural modifications toward improved antisense oligonucleotides," Perspectives in Drug Discovery and Design, Vol. 4:1-16 (1996)
35	Mazzone E, et al. "Functional changes in Duchenne muscular dystrophy: a 12-month longitudinal cohort study," Neurology 2011;77(3):250-6.
36	MCCARVILLE, M. Beth et al., "Rhabdomyosarcoma in Pediatric Patients: The Good, the Bad, and the Unusual," AJR, Vol. 176:1563-1569 (2001) (Exhibit Number 1034 filed in interferences 106008, 106007 on November 18, 2014)
37	McCLOREY, G. et al., "Antisense oligonucleotide-induced exon skipping restores dystrophin expression in vitro in a canine model of DMD," Gene Therapy, Vol. 13:1373-1381 (2006)
38	McCLOREY, G. et al., "Induced dystrophin exon skipping in human muscle explants," Neuromuscular Disorders, Vol. 16:583-590 (2006)
39	McCLOREY, Graham et al., "Splicing intervention for Duchenne muscular dystrophy," Current Opinion in Pharmacology, Vol. 5:529-534 (2005)
40	McDonald CM, et al., "Profiles of Neuromuscular Diseases, Duchenne muscular dystrophy," Am J Phys Med Rehabil 1995;74:S70-S92
41	McDonald CM, et al., "The 6-minute walk test as a new outcome measure in Duchenne muscular dystrophy," Muscle Nerve 2010;41:500-10.
42	McDonald CM, et al., "The 6-minute walk test in Duchenne/Becker muscular dystrophy: longitudinal observations," Muscle Nerve 2010;42: 966-74.
43	Mendell JR et al., "Evidence-based path to newborn screening for Duchenne muscular Dystrophy," Ann Neurol 2012;71:304-13.
44	Mendell JR, et al., "Dystrophin immunity revealed by gene therapy in Duchenne muscular dystrophy," N Engl J Med 2010;363:1429-37.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32908	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

45	Mendell JR, et al., "Randomized, double-blind six-month trial of prednisone in Duchenne's muscular dystrophy," N Engl J Med 1989;320:1592-97.
46	MENDELL, Jerry R. et al., "Eteplirsen for the Treatment of Duchenne Muscular Dystrophy," Ann. Neurol., Vol. 74:637-647 (2013) (Exhibit Number 2058 filed in interferences 106008, 106013, 106007 on November 18, 2014)
47	MENDELL, Jerry R. et al., "Eteplirsen in Duchenne Muscular Dystrophy (DMD): 144 Week Update on Six-Minute Walk Test (6MWT) and Safety," slideshow, presented at the 19th International Congress of the World Muscle Society, 17 pages (2014) (Exhibit Number 2059 filed in interferences 106008, 106013, 106007 on November 18, 2014)
48	MENDELL, Jerry R. et al., "Gene therapy for muscular dystrophy: Lessons learned and path forward," Neuroscience Letters, Vol. 527:90-99 (2012)
49	Merlini L, et al., "Early corticosteroid treatment in 4 Duchenne muscular dystrophy patients: 14-year follow-up," Muscle Nerve 2012;45:796-802.
50	Mfold illustrations for Exon 51 and Exon 53 with varying amounts of intron sequence, (University of Western Australia Exhibit 2132, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-2).

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**INFORMATION DISCLOSURE  
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Application Number # 32909	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

**CERTIFICATION STATEMENT**

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

**SIGNATURE**

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Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

/KIMBERLY CHONG/ (10/01/2017)

10/01/2017



## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Doc code: IDS

# 32911

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2016. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number	15705172
	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
	Examiner Name	K. Chong
	Attorney Docket Number	AVN-008CN41

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	1	20170009234	A1	2017-01-12	WILTON et al.		
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32912	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	K. Chong
Attorney Docket Number	AVN-008CN41

1	
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**EXAMINER SIGNATURE**

Examiner Signature	/KIMBERLY CHONG/ (10/01/2017)	Date Considered	10/01/2017
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32913	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	K. Chong
Attorney Docket Number	AVN-008CN41

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-26
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Doc code: IDS

# 32915

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2016. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number	15705172
	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	AVN-008CN41

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Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup>	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32916	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

1	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit List as of November 18, 2014, 7 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 216)
2	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit list, 7 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 213)
3	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit list, 7 pages, Patent Interference No. 106,013, dated November 18, 2014 (Doc 134)
4	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit List, 7 pages, Patent Interference Nos. 106,008, dated December 12, 2014 (Doc 221)
5	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit List, 8 pages, Patent Interference No. 106,007, dated December 12, 2014 (Doc 217)
6	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA List of Proposed Motions, Patent Interference No. 106,007, 7 pages, dated September 10, 2014 (Doc 17)
7	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA List of Proposed Motions, Patent Interference No. 106,008, 6 pages, dated September 10, 2014 (Doc 16)
8	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Miscellaneous Motion 1 (for authorization to file terminal disclaimer), 5 pages, Patent Interference No. 106,008, dated October 17, 2014 (Doc 22)
9	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 1 (For Judgment Under 35 U.S.C., section 112(a)), 40 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 210)
10	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 1 (For Judgment Under 35 § 112(a)) Patent Interference No. 106,008 (Doc 213), 38 Pages, on November 18, 2014
11	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 1 (To Maintain Interference between UWA US Patent No. 8,486,907 and AZL USSN 14/198,992), 45 pages, Patent Interference No. 106,013, dated November 18, 2014 (Doc 133)



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32917	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

12	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 2 (For Judgment Under 35 U.S.C. section 112(b)), 32 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 214)
13	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 2 (For Judgment Under 35 U.S.C. section 112(b)), 34 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 211)
14	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 3 (For judgment that Claims 11-12, 14-15, and 17-29 of Application No. 13/550,210 are barred under 35 U.S.C. section 135(b)), 25 Pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 215)
15	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Filing Priority Statement, 2 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 218)
16	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,007, July 2, 2015, pages 1-16 (Doc 469).
17	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,007, September 2, 2015, pages 1-18 (Doc 470).
18	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,008, July 2, 2015, pages 1-16 (Doc 477)
19	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,008, September 2, 2015, pages 1-18 (Doc 478).
20	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Related Proceedings, Patent Interference No. 106,007, 3 pages, dated August 1, 2014 (Doc 11)
21	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Related Proceedings, Patent Interference No. 106,008, 5 pages, dated August 7, 2014 (Doc 11)
22	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Related Proceedings, Patent Interference No. 106,013, 3 pages, dated October 14, 2014 (Doc 6)

Application Number  
# 32918

15/05172

Filing Date

2017-09-14

First Named Inventor

Stephen Donald WILTON

Art Unit

1674

Examiner Name

Not Yet Assigned

Attorney Docket Number

AVN-008CN41

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

23	US 7,960,541 (Wilton et al.), Pages 84, Exhibit Number 1002 filed in interferences 106,007 and 106,008 on November 18, 2014.
24	US 8,450,474 (Wilton et al.), Pages 95, Exhibit Number 1087 filed in interferences 106,007 and 106,008 on February 13, 2015.
25	US 8,455,634 (Wilton et al.) Pages 95, Exhibit Number 1088 filed in interferences 106,007 and 106,008 on February 13, 2015.
26	US 8,455,635 (Wilton et al.), Pages 96, Exhibit Number 1089 filed in interferences 106,007 and 106,008 on February 13, 2015.
27	US 8,455,636 (Wilton et al.), Pages 92, Exhibit Number 1003 filed in interferences 106,007 and 106,008 on November 18, 2014.
28	US 8,476,423 (Wilton et al.), Pages 95, Exhibit Number 1111 filed in interferences 106,007 and 106,008 on February 13, 2015.
29	US 8,501,703 (Bennett et al.), Pages 16, Exhibit Number 1090 filed in interferences 106,007 and 106,008 on February 13, 2015.
30	US 8,501,704 (Mourich et al.), Pages 39, Exhibit Number 1091 filed in interferences 106,007 and 106,008 on February 13, 2015.
31	US 8,524,676 (Stein et al.), Pages 28, Exhibit Number 1092 filed in interferences 106,007 and 106,008 on February 13, 2015.
32	US 8,524,880 (Wilton et al.), Pages 89, Exhibit Number 1093 filed in interferences 106,007 and 106,008 on February 13, 2015.
33	US 8,536,147 (Weller et al.), Pages 95, Exhibit Number 1094 filed in interferences 106,007 and 106,008 on February 17, 2015, Doc 251.

Application Number  
# 32919

15705172

Filing Date

2017-09-14

First Named Inventor

Stephen Donald WILTON

Art Unit

1674

Examiner Name

Not Yet Assigned

Attorney Docket Number

AVN-008CN41

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

34	US 8,592,386 (Mourich et al.), Pages 46, Exhibit Number 1095 filed in interferences 106,007 and 106,008 on February 13, 2015.
35	US 8,618,270 (Iversen et al.), Pages 28, Exhibit Number 1096 filed in interferences 106,007 and 106,008 on February 13, 2015.
36	US 8,637,483 (Wilton et al.), Pages 157, Exhibit Number 1097 filed in interferences 106,007 and 106,008 on February 13, 2015.
37	US 8,697,858 (Iversen), Pages 95, Exhibit Number 1098 filed in interferences 106,007 and 106,008 on February 13, 2015.
38	US 8,703,735 (Iversen et al.) Pages 73, Exhibit Number 1099 filed in interferences 106,007 and 106,008 on February 13, 2015.
39	US 8,741,863 (Moulton et al.), Pages 68, Exhibit Number 1100 filed in interferences 106,007 and 106,008 on February 13, 2015.
40	US 8,759,307 (Stein et al.), Pages 35, Exhibit Number 1101 filed in interferences 106,007 and 106,008 on February 13, 2015.
41	US 8,779,128 (Hanson et al.), Pages 104, Exhibit Number 1102 filed in interferences 106,007 and 106,008 on February 13, 2015.
42	US 8,785,407 (Stein et al.), Pages 35, Exhibit Number 1103 filed in interferences 106,007 and 106,008 on February 13, 2015.
43	US 8,785,410 (Iversen et al.), Pages 20, Exhibit Number 1104 filed in interferences 106,007 and 106,008 on February 13, 2015.
44	US 8,835,402 (Kole et al.), Pages 27, Exhibit Number 1105 filed in interferences 106,007 and 106,008 on February 13, 2015.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32920	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

45	US 8,865,883 (Sazani et al.), Pages 199, Exhibit Number 1106 filed in interferences 106,007 and 106,008 on February 13, 2015.
46	US 8,871,918 (Sazani et al.), Pages 195, Exhibit Number 1107 filed in interferences 106,007 and 106,008 on February 13, 2015.
47	US 8,877,725 (Iversen et al.), Pages 34, Exhibit Number 1108 filed in interferences 106,007 and 106,008 on February 13, 2015.
48	US 8,895,722 (Iversen et al.), Pages 29, Exhibit Number 1109 filed in interferences 106,007 and 106,008 on February 13, 2015.
49	US 8,906,872 (Iversen et al.), Pages 69, Exhibit Number 1110 filed in interferences 106,007 and 106,008 on February 13, 2015.
50	US Abandonment for Application No. 13/902,376, 1 page, dated June 12, 2014 (Exhibit Number 1047 filed in interferences 106008, 106007 on November 18, 2014)

If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

Examiner Signature	/KIMBERLY CHONG/ (10/01/2017)	Date Considered	10/01/2017
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32921	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

**CERTIFICATION STATEMENT**

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See attached certification statement.

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Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with 37 CFR § 1.6(a)(4).

Dated: September 22, 2017  
Electronic Signature for Amy E. Mandragouras, Esq.: /Amy E. Mandragouras, Esq./

Docket No.: AVN-008CN41  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Stephen Donald Wilton *et al.*

Application No.: 15/705,172

Confirmation No.: 2879

Filed: September 14, 2017

Art Unit: 1674

For: ANTISENSE OLIGONUCLEOTIDES FOR  
INDUCING EXON SKIPPING AND  
METHODS OF USE THEREOF

Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In compliance with 37 C.F.R. § 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the documents listed on the attached PTO/SB/08. It is respectfully requested that the documents listed on the PTO/SB/08 be expressly considered by the Examiner during the prosecution of this application, and that the documents be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

For the Examiner's convenience in reviewing this continuation application, Applicant submits a consolidated PTO/SB/08, listing all references cited during the prosecution of the parent applications. The present application is a continuation of U.S. Application No. 15/274,772, filed September 23, 2016 (Atty. Docket No. AVN-008CN37). In accordance with 37 C.F.R. §1.98(d), copies of the references previously cited by or submitted to the Office in the parent applications are not enclosed, but will be provided upon request.



Application No.: 15/705,172 (Information Disclosure Statement)

Docket No.: AVN-008CN41

Applicant calls to the attention of the Examiner the following Applications and Office Actions issued therein:

<b>Applications</b>				
<i>Examiner's Initials</i>	<i>Serial No.</i>	<i>Filing Date</i>	<i>First Named Inventor</i>	<i>Docket No.</i>
	11/570,691	January 15, 2008	Stephen Donald Wilton	AVN-008
	12/837,356	July 15, 2010	Stephen Donald Wilton	AVN-008CN
	12/837,359	July 15, 2010	Stephen Donald Wilton	AVN-008CN2
	12/860,078	August 20, 2010	Stephen Donald Wilton	AVN-008CN3
	13/168,857	June 24, 2011	Stephen Donald Wilton	AVN-008CN4
	13/168,863	June 24, 2011	Stephen Donald Wilton	AVN-008CN5
	13/270,500	October 11, 2011	Stephen Donald Wilton	AVN-008CN6
	13/270,531	October 11, 2011	Stephen Donald Wilton	AVN-008CN7
	13/270,744	October 11, 2011	Stephen Donald Wilton	AVN-008CN8
	13/270,937	October 11, 2011	Stephen Donald Wilton	AVN-008CN9
	13/270,992	October 11, 2011	Stephen Donald Wilton	AVN-008CN10
	13/271,080	October 11, 2011	Stephen Donald Wilton	AVN-008CN11
	13/727,415	December 26, 2012	Stephen Donald Wilton	AVN-008CN12
	13/741,150	January 14, 2013	Stephen Donald Wilton	AVN-008CN13
	13/826,613	March 14, 2013	Stephen Donald Wilton	AVN-008CN14
	13/826,880	March 14, 2013	Stephen Donald Wilton	AVN-008CN15
	13/902,376	May 24, 2013	Stephen Donald Wilton	AVN-008CN17
	13/963,578	August 9, 2013	Stephen Donald Wilton	AVN-008CN18

Application No.: 15/705,172 (Information Disclosure Statement)

Docket No.: AVN-008CN41

	14/086,859	November 21, 2013	Stephen Donald Wilton	AVN-008CN19
	14/178,059	February 11, 2014	Stephen Donald Wilton	AVN-008CN20
	14/223,634	March 24, 2014	Stephen Donald Wilton	AVN-008CN22
	14/273,318	May 8, 2014	Stephen Donald Wilton	AVN-008CN23
	14/273,379	May 8, 2014	Stephen Donald Wilton	AVN-008CN24
	14/316,603	June 26, 2014	Stephen Donald Wilton	AVN-008CN25
	14/316,609	June 26, 2014	Stephen Donald Wilton	AVN-008CN26
	14/317,952	June 27, 2014	Stephen Donald Wilton	AVN-008CN27
	14/740,097	June 15, 2015	Stephen Donald Wilton	AVN-008CN28
	14/852,090	September 11, 2015	Stephen Donald Wilton	AVN-008CN29RCE
	14/852,149	September 11, 2015	Stephen Donald Wilton	AVN-008CN30
	14/857,555	September 17, 2015	Stephen Donald Wilton	AVN-008CN31
	14/857,561	September 17, 2015	Stephen Donald Wilton	AVN-008CN32RCE
	14/858,250	September 18, 2015	Stephen Donald Wilton	AVN-008CN33
	15/274,719	September 23, 2016	Stephen Donald Wilton	AVN-008CN36
	15/274,772	September 23, 2016	Stephen Donald Wilton	AVN-008CN37
	15/349,535	11-11-2016	Stephen Donald Wilton	AVN-008RE
	12/605,276	October 23, 2009	Peter SAZANI	AVN-009RCE
	13/829,545	March 14, 2013	Peter SAZANI	AVN-009CN
	13/830,253	March 14, 2013	Peter SAZANI	AVN-009CN2
	14/523,610	October 24, 2014	Peter SAZANI	AVN-009DV
	14/852,257	September 11, 2015	Peter SAZANI	AVN-009DVCN1RCE

Application No.: 15/705,172 (Information Disclosure Statement)

Docket No.: AVN-008CN41

	14/852,264	September 11, 2015	Peter SAZANI	AVN-009DVCN2
	14/857,569	September 17, 2015	Peter SAZANI	AVN-009DVCN3
	14/857,590	September 17, 2015	Peter SAZANI	AVN-009DVCN4
	14/858,416	September 18, 2015	Peter SAZANI	AVN-009DVCN5
	14/743,856	June 18, 2015	R.K. BESTWICK	AVN-10PCCN
	14/213,629	March 14, 2014	E.M. KAYE	AVN-012ARCE
	14/214,567	March 14, 2014	E.M. KAYE	AVN-012BRCE
	14/213,607	March 14, 2014	R.K. BESTWICK	AVN-013A
	14/214,480	March 14, 2014	R.K. BESTWICK	AVN-013BRCE
	14/942,629	November 16, 2015	R.K. BESTWICK	AVN-013ACN
	13/509,331	July 9, 2012	S.D. WILTON	AVN-015US
	14/108,137	December 16, 2013	S.D. WILTON	AVN-015USCN
	14/944,886	November 18, 2015	S.D. WILTON	AVN-015USCN2
	14/213,641	March 14, 2014	R.K. BESTWICK	AVN-017RCE
	14/776,533	September 14, 2015	R.K. BESTWICK	AVN-017CPUS

Office Actions (copies enclosed)			
<i>Examiner's Initials</i>	<i>Serial No.</i>	<i>Date Mailed from USPTO</i>	<i>Examiner</i>
	11/570,691	August 16, 2010	Kimberly Chong
	11/570,691	March 15, 2010	Kimberly Chong
	11/570,691	May 26, 2009	Kimberly Chong
	12/837,356	May 3, 2013	Kimberly Chong
	12/837,356	April 3, 2013	Kimberly Chong
	12/837,356	August 2, 2012	Kimberly Chong
	12/837,359	March 12, 2012	Kimberly Chong
	12/837,359	October 5, 2011	Kimberly Chong
	12/837,359	March 30, 2011	Kimberly Chong
	12/837,359	December 22, 2010	Kimberly Chong
	12/860,078	February 14, 2011	Kimberly Chong
	13/168,857	July 12, 2012	Kimberly Chong
	13/168,863	March 8, 2013	Kimberly Chong
	13/168,863	October 11, 2012	Kimberly Chong
	13/168,863	August 8, 2012	Kimberly Chong

Application No.: 15/705,172 (Information Disclosure Statement)

Docket No.: AVN-008CN41

	13/270,500	March 15, 2013	Kimberly Chong
	13/270,500	July 30, 2012	Kimberly Chong
	13/270,500	March 14, 2012	Kimberly Chong
	13/270,531	June 28, 2012	Kimberly Chong
	13/270,531	March 14, 2012	Kimberly Chong
	13/270,744	April 3, 2013	Kimberly Chong
	13/270,744	August 6, 2012	Kimberly Chong
	13/270,744	March 14, 2012	Kimberly Chong
	13/270,937	February 25, 2013	Kimberly Chong
	13/270,937	June 14, 2012	Kimberly Chong
	13/270,937	March 14, 2012	Kimberly Chong
	13/270,992	April 4, 2013	Kimberly Chong
	13/270,992	July 30, 2012	Kimberly Chong
	13/270,992	March 16, 2012	Kimberly Chong
	13/271,080	March 26, 2013	Kimberly Chong
	13/271,080	July 30, 2012	Kimberly Chong
	13/271,080	March 14, 2012	Kimberly Chong
	13/727,415	February 6, 2013	Kimberly Chong
	13/741,150	March 16, 2015	Kimberly Chong
	13/741,150	September 18, 2014	Kimberly Chong
	13/741,150	April 11, 2014	Kimberly Chong
	13/741,150	September 24, 2013	Kimberly Chong
	13/826,613	July 22, 2014	Kimberly Chong
	13/826,613	January 7, 2014	Kimberly Chong
	13/826,613	July 17, 2013	Kimberly Chong
	13/826,880	June 22, 2015	Kimberly Chong
	13/826,880	January 26, 2015	Kimberly Chong
	13/826,880	April 15, 2014	Kimberly Chong
	13/826,880	September 11, 2013	Kimberly Chong
	13/902,376	June 5, 2014	Kimberly Chong
	13/902,376	January 7, 2014	Kimberly Chong
	13/902,376	July 18, 2013	Kimberly Chong
	13/963,578	September 24, 2013	Kimberly Chong
	14/086,859	June 30, 2014	Kimberly Chong
	14/086,859	January 27, 2014	Kimberly Chong
	14/178,059	March 31, 2014	Kimberly Chong
	14/223,634	April 15, 2015	Kimberly Chong
	14/273,318	October 20, 2014	Kimberly Chong
	14/273,318	July 3, 2014	Kimberly Chong
	14/273,379	July 7, 2014	Kimberly Chong
	14/316,603	March 10, 2015	Kimberly Chong
	14/316,603	September 26, 2014	Kimberly Chong

Application No.: 15/705,172 (Information Disclosure Statement)

Docket No.: AVN-008CN41

	14/316,609	March 16, 2015	Kimberly Chong
	14/316,609	October 21, 2014	Kimberly Chong
	14/317,952	March 18, 2015	Kimberly Chong
	14/317,952	November 7, 2014	Kimberly Chong
	14/740,097	November 14, 2016	Kimberly Chong
	14/740,097	April 8, 2016	Kimberly Chong
	14/740,097	November 6, 2015	Kimberly Chong
	14/852,090	April 15, 2016	Kimberly Chong
	14/852,090	January 6, 2016	Kimberly Chong
	14/852,090	October 15, 2015	Kimberly Chong
	14/852,149	November 24, 2015	Kimberly Chong
	14/857,555	April 12, 2016	Kimberly Chong
	14/857,555	November 6, 2015	Kimberly Chong
	14/857,561	April 18, 2016	Kimberly Chong
	14/857,561	March 15, 2016	Kimberly Chong
	14/857,561	February 17, 2016	Kimberly Chong
	14/857,561	January 8, 2016	Kimberly Chong
	14/857,561	October 23, 2015	Kimberly Chong
	14/858,250	November 6, 2015	Kimberly Chong
	12/605,276	June 18, 2014	J. McDonald
	12/605,276	October 18, 2013	J. McDonald
	12/605,276	December 23, 2011	J. McDonald
	12/605,276	August 24, 2011	J. McDonald
	12/605,276	February 11, 2011	J. McDonald
	13/829,545	June 6, 2014	J. McDonald
	13/830,253	June 11, 2014	J. McDonald
	13/830,253	November 26, 2013	J. McDonald
	14/523,610	May 11, 2016	J. McDonald
	14/852,257	October 27, 2015	J. McDonald
	14/852,257	October 6, 2015	J. McDonald
	14/852,264	April 21, 2016	J. McDonald
	14/852,264	October 21, 2015	J. McDonald
	14/857,569	May 6, 2016	J. McDonald
	14/857,569	November 19, 2015	J. McDonald
	14/857,590	May 16, 2016	J. McDonald
	14/857,590	November 19, 2015	J. McDonald
	14/858,416	May 4, 2016	J. McDonald
	14/858,416	October 27, 2015	J. McDonald
	14/214,567	July 7, 2016	E. Poliakova-Georgan
	14/214,567	December 3, 2015	E. Poliakova-Georgan
	14/214,567	June 24, 2015	E. Poliakova-Georgan
	14/213,607	September 15, 2015	D.H. Shin

Application No.: 15/705,172 (Information Disclosure Statement)

Docket No.: AVN-008CN41

	14/213,607	April 1, 2015	D.H. Shin
	14/213,607	September 18, 2014	D.H. Shin
	14/214,480	August 2, 2016	D.H. Shin
	14/214,480	October 19, 2015	D.H. Shin
	14/214,480	April 17, 2015	D.H. Shin
	14/214,480	September 19, 2014	D.H. Shin
	14/942,629	August 16, 2016	D.H. Shin
	13/509,331	September 16, 2013	T.A. Vivlemore
	13/509,331	January 28, 2013	T.A. Vivlemore
	14/108,137	April 29, 2015	T.A. Vivlemore
	14/108,137	October 9, 2015	T.A. Vivlemore
	14/108,137	October 3, 2014	T.A. Vivlemore
	14/944,886	April 27, 2017	T.A. Vivlemore
	14/944,886	September 30, 2016	T.A. Vivlemore
	14/213,641	August 1, 2016	D.H. Shin
	14/213,641	October 16, 2015	D.H. Shin
	14/213,641	March 31, 2015	D.H. Shin
	14/213,641	September 18, 2014	D.H. Shin
	14/213,629	May 23, 2016	E. Poliakova-Georgan
	14/213,629	August 21, 2015	E. Poliakova-Georgan
	14/213,629	December 29, 2014	E. Poliakova-Georgan
	14/743,856	August 1, 2016	A. Hudson Bowman
	14/776,533	February 28, 2017	D. Shin
	14/776,533	August 3, 2016	D. Shin
	15/274,719	December 16, 2016	K. Chong
	15/274,772	December 30, 2016	K. Chong
	15/274,772	September 18, 2017	K. Chong

The Examiner is requested to review the file histories of these applications, including cited references, Office Actions, Responses, etc., and is asked to contact Applicant's Attorney if the Examiner would like the Applicant to supply copies of any or all of the information included in any of these applications. For any of these applications, if Applicant's Attorney is not contacted by the Examiner with such a request, then it will be concluded that the Examiner has reviewed or will review the file content of these applications.

Applicant respectfully requests that the Examiner initial the blank columns next to the cited Applications and Office Actions, to indicate that the information has been considered by the Examiner. Alternatively, Applicant requests that the Examiner insert the phrase, "All references



Application No.: 15/705,172 (Information Disclosure Statement)

Docket No.: AVN-008CN41

considered except where lined through," on each page of the Information Disclosure Statement, along with the Examiner's initials.

The filing of this Information Disclosure Statement is not to be interpreted as a representation that the cited documents are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any documents herein be construed *per se* as a representation that such document is prior art. Moreover, Applicant understands the Examiner will make an independent evaluation of the cited documents.

This Information Disclosure Statement is filed within three months of the U.S. filing date (37 C.F.R. § 1.97(b)(1)). Applicant believes no fee is due with this statement.

Dated: September 22, 2017

Respectfully submitted,

/KIMBERLY CHONG/ (10/01/2017)  
10/01/2017

Electronic signature: /Amy E. Mandragouras, Esq./  
Amy E. Mandragouras, Esq.  
Registration No.: 36,207  
NELSON MULLINS RILEY & SCARBOROUGH LLP  
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(617) 217-4699 (Fax)  
Attorney/Agent For Applicant



Doc code: IDS

# 32931

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2016. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number	15705172
	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	AVN-008CN41

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32932	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

1	University of Western Australia v. Academisch Ziekenhuis Leiden, Miscellaneous Order under 37 CFR 41.104(a), 4 pages, Patent Interference Nos. 106,007 and 106,008, dated December 15, 2014
2	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Authorizing Motions, Patent Interference No. 106,007, 3 pages, dated September 26, 2014 (Doc 20)
3	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Authorizing Motions, Patent Interference No. 106,007, 6 pages, dated September 23, 2014 (Doc 19)
4	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Authorizing Motions, Patent Interference No. 106,008, 6 pages, dated September 23, 2014 (Doc 18)
5	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Miscellaneous, 2 pages, Patent Interference Nos. 106,007, 106,008, 106,013, dated November 14, 2014
6	University of Western Australia v. Academisch Ziekenhuis Leiden, Order to Show Cause- 37 CFR§ 41.104(a), filed in Patent Interference No. 106,013, June 22, 2015, pages 1-3 (Doc 193).
7	University of Western Australia v. Academisch Ziekenhuis Leiden, Redeclaration, Patent Interference No. 106,008, 2 pages, dated September 23, 2014 (Doc 19)
8	University of Western Australia v. Academisch Ziekenhuis Leiden, Second Declaration of Matthew J. A. Wood, M.D., D. PHIL., Patent Interference Nos. 106,007 and 106,008, 78 pages, dated February 17, 2015 (Exhibit Number 2116 filed in interferences 106,007 and 106,008, on February 17, 2015.
9	University of Western Australia v. Academisch Ziekenhuis Leiden, Statement Concerning Initial Settlement Discussions, 3 pages, Patent Interference No. 106,013, (Doc 136), dated December 30, 2014.
10	University of Western Australia v. Academisch Ziekenhuis Leiden, Statement Concerning Settlement Discussions, 3 pages, Patent Interference No. 106,007, (Doc 242), dated December 30, 2014.
11	University of Western Australia v. Academisch Ziekenhuis Leiden, Statement Concerning Settlement Discussions, 3 pages, Patent Interference No. 106,008, (Doc 246), dated December 30, 2014.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32933	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

12	University of Western Australia v. Academisch Ziekenhuis Leiden, Statement Concerning Subsequent Settlement Discussions, filed in Patent Interference No. 106,013, August 24, 2015, pages 1-3 (Doc 195).
13	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Response to Order to Show Cause, filed in Patent Interference No. 106,013, July 20, 2015, pages 1-28 (Doc 194).
14	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 10, 2015, filed in Patent Interference No. 106,007, April 10, 2015, pages 1-10 (Doc 456).
15	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 10, 2015, filed in Patent Interference No. 106,008, April 10, 2015, pages 1-10 (Doc 464).
16	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 3, 2015, filed in Interference 106007, April 3, 2015, pages 1-10 (Doc 431).
17	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 3, 2015, filed in Interference 106008, April 3, 2015, pages 1-10 (Doc 439).
18	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 3, 2015, filed in Interference 106013, April 3, 2015, pages 1-10 (Doc 153).
19	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List As of October 29, 2015, filed in Patent Interference No. 106,013, October 29, 2015, pages 1-10 (Doc 199).
20	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Miscellaneous Motion 4 (to exclude evidence), filed in Patent Interference No. 106,007, April 10, 2015, pages 1-21 (Doc 455).
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32934	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

23	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 1 (Regarding Patentability Under 35 U.S.C. § 102/103), 39 pages, Patent Interference No. 106,008, (Doc 402), dated February 17, 2015
24	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 2 (To Retain UWA's Benefit of AU 2004903474), 31 pages, Patent Interference No. 106,008, (Doc 403), dated February 17, 2015
25	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 2 (To Retain UWA's Benefit of AU 2004903474), 37 pages, Patent Interference No. 106,007, (Doc 394), dated February 17, 2015
26	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 3 (Regarding Patentability Under 35 U.S.C. § 101), 22 pages, Patent Interference No. 106,007, (Doc 395), dated February 17, 2015
27	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 3 (Regarding Patentability Under 35 U.S.C. § 101), 22 pages, Patent Interference No. 106,008, (Doc 404), dated February 17, 2015
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29	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 4 (To deny entry of AZL's Proposed New Claims 30 and 31), 36 pages, Patent Interference No. 106,008, (Doc 405), dated February 17, 2015
30	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 1 (to AZL Opposition 1), filed April 3, 2015 in Interference 106007, pages 1-28 (Doc 428).
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32935	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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36	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 3 (to institute an Interference) filed April 3, 2015 in Interference 106007, pages 1-17 (Doc 430).
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43	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Revised Designation of Lead and Backup Counsel, 4 pages, Patent Interference No. 106,007, (Doc 415), dated March 10, 2015.
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32936	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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46	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia, Exhibit List as of February 17, 2015, 8 pages, Patent Interference No. 106,007, (Doc No. 398) dated February 17, 2015.
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48	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Clean Copy of Involved Claims and Sequence, Patent Interference No. 106,007, 8 pages, dated August 1, 2014 (Doc 12)
49	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Clean Copy of Involved Claims and Sequence, Patent Interference No. 106,013, 7 pages, dated October 14, 2014 (Doc 7)
50	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Clean Copy of Involved Claims and Sequences, Patent Interference No. 106,008, 8 pages, dated August 7, 2014 (Doc 12)

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32937	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

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/KIMBERLY CHONG/ (10/01/2017)

10/01/2017



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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number	15705172
	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	AVN-008CN41

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	1	2000-325085	JP	A	2000-11-28	MATSUO MASAFUMI, ET AL.		
	2	2002-010790	JP	A	2002-01-15	Matsuo Masafumi		×
	3	2002-325582	JP	A	2002-11-12	MATSUO, MASAFUMI, ET AL.		□

Application Number # 32940		15/05172
Filing Date		2017-09-14
First Named Inventor	Stephen Donald WILTON	
Art Unit	1674	
Examiner Name	Not Yet Assigned	
Attorney Docket Number	AVN-008CN41	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

4	2002-340857	JP	A	2002-11-27	Matsushita Electric Ind Co Ltd	<input checked="" type="checkbox"/>
5	2002-529499	JP	A	2002-09-10	Eli Lilly and Company	<input checked="" type="checkbox"/>
6	2004-509622	JP	A	2004-04-02	Academisch Ziekenhuis Leiden	<input checked="" type="checkbox"/>
7	2010-268815	JP	A	2010-12-02	MATSUO MASAFUMI	<input type="checkbox"/>
8	2011-101655	JP	A	2011-05-26	Academisch Ziekenhuis Leiden	<input checked="" type="checkbox"/>
9	2011-200235	JP	A	2011-10-13	Academisch Ziekenhuis Leiden	<input checked="" type="checkbox"/>
10	2014-054250	JP	A	2014-03-27	Nippon Shinyaku Co Ltd,	<input checked="" type="checkbox"/>
11	2014-111638	JP	A	2014-06-19	Academisch, Ziekenhuis Leiden et al.	<input checked="" type="checkbox"/>
12	2014-138589	JP	A	2014-07-31	Academisch, Ziekenhuis Leiden	<input checked="" type="checkbox"/>
13	4777777	JP	B2	2011-09-21	Kobe University	<input checked="" type="checkbox"/>
14	4846965	JP	B2	2011-12-28	ACADEMISCH ZIEKENHUIS LEIDEN	<input type="checkbox"/>

Application Number # 32941		15/05172
Filing Date		2017-09-14
First Named Inventor	Stephen Donald WILTON	
Art Unit	1674	
Examiner Name	Not Yet Assigned	
Attorney Docket Number	AVN-008CN41	

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STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

15	5138722	JP	B2	2013-02-06	Matsuo Masafumi,	<input checked="" type="checkbox"/>
16	5378423	JP	B2	2013-12-25	ACADEMISCH ZIEKENHUIS LEIDEN	<input type="checkbox"/>
17	00/15780	WO	A1	2000-03-23	University College London	<input type="checkbox"/>
18	00/44897	WO	A1	2000-08-03	AVI Biopharma, Inc.	<input type="checkbox"/>
19	00/78341	WO	A1	2000-12-28	Murdoch Childrens Research Institute	<input type="checkbox"/>
20	01/49775	WO	A2	2001-07-12	AVI Biopharma, Inc.	<input type="checkbox"/>
21	01/72765	WO	A1	2001-10-04	ISIS Pharmaceuticals, Inc.	<input type="checkbox"/>
22	01/83503	WO	A2	2001-11-08	Hybridon, Inc	<input type="checkbox"/>
23	01/83740	WO	A2	2001-11-08	AVI Biopharma, Inc.	<input type="checkbox"/>
24	02/018656	WO	A2	2002-03-07	AVI Biopharma, Inc.	<input type="checkbox"/>
25	02/24906	WO	A1	2002-03-28	Academisch Ziekenhuis Leiden	<input type="checkbox"/>

Application Number # 32942		15/05172
Filing Date		2017-09-14
First Named Inventor	Stephen Donald WILTON	
Art Unit	1674	
Examiner Name	Not Yet Assigned	
Attorney Docket Number	AVN-008CN41	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

26	02/29406	WO	A1	2002-04-11	Murto, James	<input type="checkbox"/>
27	03/053341	WO	A2	2003-07-03	Isis Pharmaceuticals, Inc.	<input type="checkbox"/>
28	04/048570	WO	A1	2004-06-10	Kobe University	<input checked="" type="checkbox"/>
29	04/083432	WO	A1	2004-09-30	Academisch Ziekenhuis Leiden	<input type="checkbox"/>
30	04/083446	WO	A2	2004-09-30	Academisch Ziekenhuis Leiden	<input type="checkbox"/>
31	2005/115479	WO	A2	2005-12-08	Avi Biopharma, Inc	<input type="checkbox"/>
32	2006/000057	WO	A1	2006-01-05	University of Western Australia	<input type="checkbox"/>
33	2006/021724	WO	A2	2006-03-02	Genethon et al.	<input checked="" type="checkbox"/>
34	2006/112705	WO	A2	2006-10-26	Academisch Ziekenhuis Leiden	<input type="checkbox"/>
35	2007/058894	WO	A2	2007-05-24	The University of North Carolina at Chapel Hill et	<input type="checkbox"/>
36	2007/133812	WO	A2	2007-11-22	Philadelphia Health & Education Corporation, D/ B/A	<input type="checkbox"/>

Application Number # 32943		15/05172
Filing Date		2017-09-14
First Named Inventor	Stephen Donald WILTON	
Art Unit	1674	
Examiner Name	Not Yet Assigned	
Attorney Docket Number	AVN-008CN41	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

37	2007/135105	WO	A1	2007-11-29	Academisch Ziekenhuis Leiden	<input type="checkbox"/>
38	2008/036127	WO	A2	2008-03-27	Avi Biopharma, Inc.	<input type="checkbox"/>
39	2009/054725	WO	A2	2009-04-30	Academisch Ziekenhuis Leiden et al.	<input type="checkbox"/>
40	2009/101399	WO	A1	2009-08-20	Isis Innovation Limited	<input type="checkbox"/>
41	2009/139630	WO	A2	2009-11-19	Prosensa Technologies B.V. et al.	<input type="checkbox"/>
42	2010/048586	WO	A1	2010-04-29	AVI Biopharma, Inc.	<input type="checkbox"/>
43	2010/050801	WO	A1	2010-05-06	Prosensa Technologies B.V. et al.	<input type="checkbox"/>
44	2010/050802	WO	A2	2010-05-06	Academisch Ziekenhuis Leiden et al.	<input type="checkbox"/>
45	2010/115993	WO	A1	2010-10-14	Association Institut de Myologie et al.	<input type="checkbox"/>
46	2010/123369	WO	A1	2010-10-28	Prosensa Technologies B.V.	<input type="checkbox"/>
47	2010/136415	WO	A1	2010-12-02	Universita Degli Studi di Roma "La Sapienza"	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32944	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

48	2010/136417	WO	A1	2010-12-02	Universita Degli Studi di Roma "La Sapienza"	<input type="checkbox"/>
49	2010/150231	WO	A1	2010-12-29	Universita Degli Studi di Ferrara	<input type="checkbox"/>
50	2011/024077	WO	A2	2011-03-03	Inserm (Institut National de la Sante et de la Rec	<input type="checkbox"/>

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**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1	AON PS1966 Mass Spectrometry Data, Pages 8, Exhibit Number 1154 filed in Interferences 106,007 and 106,008 on February 16, 2015.	
	2	AON PS1966 UPLC Data, Pages 2, Exhibit Number 1165 filed in Interferences 106,007 and 106,008 on February 16, 2015.	
	3	AON PS1967 Mass Spectrometry Data, Pages 7, Exhibit Number 1155 filed in Interferences 106,007 and 106,008 on February 16, 2015.	
	4	AON PS1967 UPLC Data, Pages 2, Exhibit Number 1166 filed in Interferences 106,007 and 106,008 on February 16, 2015.	
	5	AON PS229 (h53AON1) HPLC Chromatograph Pages 2, Exhibit Number 1140 filed in Interferences 106,007 and 106,008 on February 16, 2015.	
	6	AON PS229 (h53AON1) HPLC Method Report, Pages 3, Exhibit Number 1139 filed in Interferences 106,007 and 106,008 on February 16, 2015.	



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32945	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

7	AON PS229 (h53AON1) Mass Spectrometry Data, Pages 3, Exhibit Number 1142 filed in Interferences 106,007 and 106,008 on February 16, 2015.
8	AON PS229 (h53AON1) Synthesis Laboratory Notebook Entry, Pages 1, Exhibit Number 1137 filed in Interferences 106,007 and 106,008 on February 16, 2015.
9	AON PS229L (h53AON229L) Certificate of Analysis, Pages 1, Exhibit Number 1129 filed in Interferences 106,007 and 106,008 on February 17, 2015.
10	AON PS43 (h51AON1) Certificate of Analysis, Pages 1, Exhibit Number 1134 filed in Interferences 106,007 and 106,008 on February 16, 2015.
11	AON PS43 (h51AON1) HPLC Chromatogram, Pages 1, Exhibit Number 1131 filed in Interferences 106,007 and 106,008 on February 17, 2015.
12	AON PS43 (h51AON1) HPLC Method Report, Pages 4, Exhibit Number 1130 filed in Interferences 106,007 and 106,008 on February 17, 2015.
13	AON PS43 (h51AON1) Mass Spectrometry Data, Pages 3, Exhibit Number 1135 filed in Interferences 106,007 and 106,008 on February 16, 2015.
14	AON PS43 (h51AON1) UPLC-UV Data, Pages 2, Exhibit Number 1136 filed in Interferences 106,007 and 106,008 on February 16, 2015.
15	AONs PS1958, PS1959, PS1960, PS1961, PS1962, PS1963, PS1964, PS1965, PS1966, and PS1967 HPLC Method Report, Pages 3, Exhibit Number 1143 filed in Interferences 106,007 and 106,008 on February 16, 2015.
16	Applicant-Initiated Interview Summary dated April 8, 2013 in U.S. Application Serial No. 13/094,548, (University of Western Australia Exhibit 2144, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-11).
17	Arechavala-Gomez V, et al., "Immunohistological intensity measurements as a tool to assess sarcolemma-associated protein expression," Neuropathol Appl Neurobiol 2010;36: 265-74.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32946	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32947	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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Application Number # 32948	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

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44	Claim Chart 13/550,210, Pages 45, Exhibit Number 1217 filed in Interferences 106,007 and 106,008 on February 17, 2015.
45	Claim Chart, US 7,807,816, 14 pages (Exhibit Number 1063 filed in interferences 106008, 106007 on November 18, 2014)
46	Claim Chart, US 7,960,541, 17 pages (Exhibit Number 1064 filed in interferences 106008, 106007 on November 18, 2014)
47	Claim Chart, US 8,455,636, 32 pages (Exhibit Number 1062 filed in interferences 106008, 106007 on November 18, 2014)
48	Claim Comparison Chart - Claims 11 and 29 in 13/550,210, Pages 1, Exhibit Number 1226 filed in Interferences 106,007 and 106,008 on February 17, 2015.
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32949	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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Application Number # 32950	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

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PTO/SB/08a (03-15)

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	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	AVN-008CN41

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Application Number # 32953	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

1	Transcript of 2nd Deposition of Erik J. Sontheimer, Ph.D., dated March 12, 2015, (Academisch Ziekenhuis Leiden Exhibit 1231, filed April 3, 2015 in Interference 106007 and 106008, pages 1-185).
2	Transcript of 2nd Deposition of Matthew J.A. Wood, M.D., D. Phil, dated March 5, 2015, (Academisch Ziekenhuis Leiden Exhibit 1230, filed April 3, 2015 in Interference 106007 and 106008, pages 1-117).
3	Transcript of December 12, 2014 Teleconference with Administrative Patent Judge Schafer (rough draft) (previously filed in Int. No. 106,008 as Ex. 2114), Pages 28 Exhibit Number 1001 filed in Interference 106,013 on February 17, 2015.
4	Transcript of the January 21, 2015 deposition of Erik Sontheimer, Ph.D., Patent Interference Nos. 106,007 and 106,008, 98 pages, dated January 21, 2015 (Exhibit Number 2122 filed in interferences 106,007 and 106,008 on February 17, 2015.
5	Transcript of the March 11, 2015 deposition of Judith van Deutekom, Ph.D., (University of Western Australia Exhibit 2141, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-168).
6	Transcript of the March 12, 2015 deposition of Erik J. Sontheimer, Ph.D., (University of Western Australia Exhibit 2142, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-183).
7	Transcript of the March 5, 2015 deposition of Matthew J. A. Wood, M.D., D. PHIL., (University of Western Australia Exhibit 2146, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-115).
8	Transfection of AON, Pages 1, Exhibit Number 1170 filed in Interferences 106,007 and 106,008 on February 16, 2015.
9	U.S. Food and Drug Administration Presentation at Peripheral and Central Nervous System Drugs Advisory Committee, April 25, 2016, 178 pages.
10	U.S. Food and Drug Administration Statement, dated December 30, 2014 (2 pages), Exhibit Number 1204 filed in Interferences 106,007 and 106,008 on February 17, 2015.
11	U.S. Patent Application No. 12/198,007, as-filed August 25, 2008 ("the '007 Application") (Exhibit Number 1073 filed in interferences 106008, 106007 on December 23, 2014)

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32954	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

12	U.S. Patent Application No. 12/976,381, as-filed December 22, 2010 ("the '381 Application") (Exhibit Number 1074 filed in interferences 106008, 106007 on December 23, 2014)
13	U.S. Patent Application Publication No. 2001/0056077 ("Matsuo") (Exhibit Number 1080 filed in interferences 106008, 106007 on December 23, 2014)
14	U.S. Patent Application Publication No. 2002/0049173 ("Bennett et al.") (Exhibit Number 1081 filed in interferences 106008, 106007 on December 23, 2014)
15	U.S. Patent No. 5,190,931 ("the '931 Patent") (Exhibit Number 1069 filed in interferences 106008, 106007 on December 23, 2014)
16	U.S. Patent No. 7,001,761 (the "Xiao" Patent) (Exhibit Number 1070 filed in interferences 106008, 106007 on December 23, 2014)
17	University of Western Australia Objections to Opposition Evidence, served on February 24, 2015 filed in Interference No. 106,007, Exhibit 2150, filed April 10, 2015 in Interference Nos. 106007 and 106008, pages 1-15.
18	University of Western Australia Objections to Opposition Evidence, served on February 24, 2015, filed in Interference No. 106,008, Exhibit 2151, filed April 10, 2015, in Interference Nos. 106007 and 106008, pages 1-15.
19	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision - Motions - 37 C.F.R. § 41.125(a), filed in Patent Interference No. 106008, September 20, 2016, pages 1-20 (Doc 480)
20	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision - Motions - 37 CFR § 41.125(a) (Substitute), filed in Patent Interference No. 106007, May 12, 2016, pages 1-53 (Doc 476)
21	University of Western Australia v. Academisch Ziekenhuis Leiden, Judgment - Motions - 37 C.F.R. § 41.127 filed in Patent Interference No. 106008, September 20, 2016, pages 1-3 (Doc 481)
22	University of Western Australia v. Academisch Ziekenhuis Leiden, Judgment - Motions - 37 CFR § 41.127, filed in Patent Interference No. 106007, April 29, 2016, pages 1-3 (Doc 474)

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32955	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

23	European Response, Application No. 13160338.3, 4 pages, dated June 26, 2014 (Exhibit Number 2085 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
24	University of Western Australia v. Academisch Ziekenhuis Leiden, Redecaration - 37 CFR 41.203(c), filed in Patent Interference No. 106007, April 29, 2016, pages 1-2 (Doc 473)
25	University of Western Australia v. Academisch Ziekenhuis Leiden, Withdrawal and Reissue of Decision on Motions, filed in Patent Interference No. 106007, May 12, 2016, pages 1-2 (Doc 475)
26	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits (as of Apr. 3, 2015), filed in Patent Interference No. 106,007, April 3, 2015, pages 1-18, (Doc 423).
27	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits (as of Apr. 3, 2015), filed in Patent Interference No. 106,008, April 3, 2015, pages 1-18 (Doc 435).
28	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 18 pages, Patent Interference No. 106,007, (Doc 391), dated February 17, 2015.
29	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 18 pages, Patent Interference No. 106,008, (Doc 398), dated February 17, 2015.
30	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 3 pages, Patent Interference No. 106,013, (Doc 147), dated February 17, 2015.
31	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Notice of Service of Supplemental Evidence, 3 pages, Patent Interference No. 106,007 (Doc 414), dated March 9, 2015.
32	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Notice of Service of Supplemental Evidence, 3 pages, Patent Interference No. 106,008 (Doc 422), dated March 9, 2015.
33	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 1 (35 U.S.C. § 112(a)), 83 pages, Patent Interference No. 106,008, (Doc 400), dated February 17, 2015

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32956	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

34	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 1 (35 U.S.C. § 112(a)), 93 pages, Patent Interference No. 106,007, (Doc 392), dated February 17, 2015
35	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 1 (Standing Order ¶ 203.1 and 37 C.F.R. § 41.202(a) and (e)), 20 pages, Patent Interference No. 106,013, (Doc 148), dated February 17, 2015
36	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 2 (Indefiniteness), 31 pages, Patent Interference No. 106,007, (Doc 396), dated February 17, 2015
37	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 2 (Indefiniteness), 32 pages, Patent Interference No. 106,008, (Doc 401), dated February 17, 2015
38	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 3 (35 U.S.C. §135(b)), 44 pages, Patent Interference No. 106,008, (Doc 397), dated February 17, 2015
39	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 3 (Standing Order § 203.1 and 37 C.F.R. § 41.202(a) and (e)), 20 pages, Patent Interference No. 106,007, (Doc 389), dated February 17, 2015.
40	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. §§ 102 and 103), dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-17 (Doc 431).
41	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. §§ 102 and 103), dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-17 (Doc 424).
42	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 2 (To Deny the Benefit of AU 2004903474), dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-11(Doc 425).
43	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 2 (To Deny the Benefit of AU 2004903474), dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-12 (Doc 432).
44	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 3 (For Judgment of Unpatentability based on Myriad) dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-12 (Doc 426).

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32957	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

45	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 3 (For Judgment of Unpatentability based on Myriad) dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-13 (Doc 433).
46	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 4 (In Support of Responsive Motion 4 to Add Two New Claims) dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-17 (Doc 427).
47	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 4 (In Support of Responsive Motion 4 to Add Two New Claims) dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-17 (Doc 434).
48	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Request For Oral Argument, filed in Patent Interference No. 106,007, April 10, 2015, pages 1-3 (Doc 454).
49	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Request For Oral Argument, filed in Patent Interference No. 106,008, April 10, 2015, pages 1-3 (Doc 462).
50	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Responsive Motion 4 (To Add Two New Claims), 57 pages, Patent Interference No. 106,008, (Doc 245), dated December 23, 2014.

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**EXAMINER SIGNATURE**

Examiner Signature	/KIMBERLY CHONG/ (10/01/2017)	Date Considered	10/01/2017
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32958	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

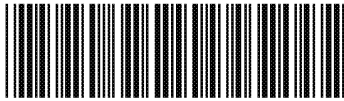


## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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<b>Search Notes</b> 	<b>Application/Control No.</b> 15705172	<b>Applicant(s)/Patent Under Reexamination</b> WILTON ET AL.
	<b>Examiner</b> KIMBERLY CHONG	<b>Art Unit</b> 1674

CPC- SEARCHED		
Symbol	Date	Examiner
C07H 21/04	9/29/2017	KC

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

\* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

SEARCH NOTES		
Search Notes	Date	Examiner
SEQ ID No. 195	9/29/2017	KC
PALM inventor name search	9/29/2017	KC

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

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Doc code: IDS

# 32961

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number	15705172
	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	AVN-008CN41

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Application Number # 32962	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

1	US Amendment After Non-Final Action for Application No. 11/233,495, 31 pages, dated June 24, 2010 (Exhibit Number 2073 filed in interferences 106008, 106013, 106007 on November 18, 2014)
2	US Amendment for Application No. 11/233,495, 15 pages, dated April 1, 2009 (Exhibit Number 2071 filed in interferences 106008, 106013, 106007 on November 18, 2014)
3	US Amendment for Application No. 11/233,495, 19 pages, dated October 31, 2007 (Exhibit Number 2070 filed in interferences 106008, 106013, 106007 on November 18, 2014)
4	US Amendment for Application No. 11/233,495, 19 pages, dated September 16, 2009 (Exhibit Number 2072 filed in interferences 106008, 106013, 106007 on November 18, 2014)
5	US Amendment for Application No. 11/233,495, 9 pages, dated October 31, 2007 (Exhibit Number 2070 filed in interferences 106008, 106013, 106007 on November 18, 2014)
6	US Amendment for Application No. 11/570,691, 9 pages, dated June 15, 2010 (Exhibit Number 1043 filed in interferences 106008, 106007 on November 18, 2014)
7	US Amendment for Application No. 13/271,080, 30 pages, dated January 30, 2013 (Exhibit Number 1049 filed in interferences 106008, 106007 on November 18, 2014)
8	US Amendment for Application No. 13/902,376, 36 pages, dated March 21, 2014 (Exhibit Number 1046 filed in interferences 106008, 106007 on November 18, 2014)
9	US Amendment in Response to Advisory Action for Application No. 11/233,495, 23 pages, dated March 14, 2011 (Exhibit Number 2074 filed in interferences 106008, 106013, 106007 on November 18, 2014)
10	US Amendments to the Claims for Application No. 11/233,495, 4 pages, dated May 8, 2014 (Exhibit Number 2077 filed in interferences 106008, 106013, 106007 on November 18, 2014)
11	US Amendments to the Claims for Application No. 14/198,992, 3 pages, dated July 16, 2014 (Exhibit Number 2079 filed in interferences 106008, 106013, 106007 on November 18, 2014)

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32963	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

12	US Applicant-Initiated Interview Summary and Notice of Allowance for Application No. 13/550,210, 9 pages dated May 19, 2014 (Exhibit Number 2076 filed in interferences 106008, 106013, 106007 on November 18, 2014)
13	US application as-filed and Preliminary Amendment for Application No. 13/550,210, 59 pages dated July 16, 2012 (Exhibit Number 2087 filed in interferences 106008, 106013, 106007 on November 18, 2014)
14	US Application as-filed for application No. 14/198,992, 52 pages, dated March 6, 2014 (Exhibit Number 2086 filed in interferences 106008, 106013, 106007 on November 18, 2014)
15	US Application as-filed, Application Data Sheet, and Preliminary Amendment for Application No. 12/837,359, 101 pages, dated July 15, 2010 (Exhibit Number 2100 filed in interferences 106008, 106013, 106007 on November 18, 2014)
16	US Application for Letters Patent for Application No. 11/233,495 as-filed and preliminary amendment, 77 pages, dated September 21, 2005 (Exhibit Number 2095 filed in interferences 106008, 106013, 106007 on November 18, 2014)
17	US Application No. 11/233,495, 74 pages; excerpts of prosecution history for including: US Supplemental Amendment and Response dated May 8, 2014; Second Supplemental Response dated July 5, 2013; Supplemental Amendment dated June 26, 2013; Amendment after Non-final Action dated November 1, 2010; Amendment under 35 USC 1.114 dated September 16, 2009 (Exhibit Number 2054 filed in interferences 106008, 106013, 106007 on November 18, 2014)
18	US Application No. 14/198,992, 17 pages; excerpts of prosecution history including: Supplemental Amendment dated July 16, 2014; Response to Non-Final Office Action dated July 14, 2014 (Exhibit Number 2056 filed in interferences 106008, 106013, 106007 on November 18, 2014)
19	US Application No. 14/248,279, 29 pages; excerpts of prosecution history including: Amendment under 37 CFR 1.312 dated September 19, 2014; Amendment in Response to Final Office Action dated August 7, 2014; Declaration under 37 CFR 1.132 dated May 26, 2014; Declaration under 37 CFR 1.132 dated May 27, 2014; Response dated June 3, 2014 (Exhibit Number 2057 filed in interferences 106008, 106013, 106007 on November 18, 2014)
20	US Application No. 13/550,210, 27 pages; excerpts of prosecution history including: Response and Amendment dated May 12, 2014; Response to Non-Final Office Action dated January 21, 2014; Second Preliminary Amendment dated January 3, 2013 (Exhibit Number 2055 filed in interferences 106008, 106013, 106007 on November 18, 2014)
21	US claim amendments for Application No. 13/550,210, 3 pages, dated May 12, 2014 (Exhibit Number 2078 filed in interferences 106008, 106013, 106007 on November 18, 2014)
22	US Claims for Application No. 12/976,381, 1 page, dated December 22, 2010 (Exhibit Number 2065 filed in interferences 106008, 106013, 106007 on November 18, 2014)

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32984	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

23	US Declaration of Richard K. Bestwick, for Application No. 11/570,691, 5 pages, dated June 15, 2010 (Exhibit Number 1044 filed in interferences 106008, 106007 on November 18, 2014)
24	US E-mail from Patent Trial and Appeal Board to Danny Huntington, 2 pages, dated October 9, 2014 (Exhibit Number 2002 filed in interferences 106008 on October 17, 2014)
25	US Non-Final Office Action for Application No. 11/570,691, 16 pages, dated March 15, 2010 (Exhibit Number 1042 filed in interferences 106008, 106007 on November 18, 2014)
26	US Office Action for Application No. 13/271,080, 25 pages, dated July 30, 2012 (Exhibit Number 1048 filed in interferences 106008, 106007 on November 18, 2014)
27	US Office Action for Application No. 13/550,210, 12 pages, dated September 27, 2013 (Exhibit Number 2080 filed in interferences 106008, 106013, 106007 on November 18, 2014)
28	US Office Action for Application No. 13/902,376, 7 pages, dated January 7, 2014 (Exhibit Number 1045 filed in interferences 106008, 106007 on November 18, 2014)
29	US Patent Application No. 12/198,007 as-filed, 64 pages, dated August 25, 2008 (Exhibit Number 2092 filed in interferences 106008, 106013, and 106007 on November 18, 2014)
30	US Preliminary Amendment and application as-filed for Application No. 12/976,381, 64 pages, dated December 22, 2010 (Exhibit No. 2089 filed in interferences 106007, 106008, and 106013 on November 18, 2014)
31	US Preliminary Amendment for Application No. 11/233,495, 10 pages, dated September 21, 2005 (Exhibit Number 2069 filed in interferences 106008, 106013, 106007 on November 18, 2014)
32	US Preliminary Remarks for Application No. 14/198,992, 1 page, dated March 6, 2014 (Exhibit Number 2097 filed in interferences 106008, 106013, 106007 on November 18, 2014)
33	US Proposed Terminal Disclaimer for Application No. 12/860,078, 2 pages, dated October 17, 2014 (Exhibit Number 2001 filed in interference 106008 on October 17, 2014)



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32965	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

34	US Remarks for Application No. 14/248,279, 2 pages, dated August 27, 2014 (Exhibit Number 2110 filed in interferences 106008, 106013, 106007 on November 18, 2014)
35	US Response and amendments for Application No. 13/550,210, 12 pages, dated January 21, 2014 (Exhibit Number 2063 filed in interferences 106008, 106013, 106007 on November 18, 2014)
36	US Revised Figure 4H, US Application No. 13/271,080, 1 page (Exhibit Number 1050 filed in interferences 106008, 106007 on November 18, 2014)
37	US Terminal Disclaimer for Application No. 14/198,992, 1 page, dated July 15, 2014 (Exhibit Number 2096 filed in interferences 106008, 106013, 106007 on November 18, 2014)
38	US Terminal Disclaimer for Application No. 14/248,279, 1 page, dated August 7, 2014 (Exhibit Number 2109 filed in interferences 106008, 106013, 106007 on November 18, 2014)
39	US Track One Request, Application as-filed, and Application Data Sheet for Application No. 14/248,279, 68 pages, dated April 8, 2014 (Exhibit Number 2108 filed in interferences 106008, 106013, 106007 on November 18, 2014)
40	US Transmittal, application as-filed, and Preliminary Amendment for Application No. 11/570,691, 102 pages, dated December 15, 2006 (Exhibit Number 2103 filed in interferences 106008, 106013, 106007 on November 18, 2014)
41	US Transmittal, application as-filed, and Preliminary Amendment for Application No. 13/270,992, 101 pages, dated October 11, 2011 (Exhibit Number 2098 filed in interferences 106008, 106013, 106007 on November 18, 2014)
42	US Transmittal, application as-filed, and Preliminary Amendment for Application No. 13/271,080, 115 pages, dated October 11, 2011 (Exhibit Number 2111 filed in interferences 106008, 106013, 106007 on November 18, 2014)
43	US Updated Filing Receipt for Application No. 13/550,210, 3 pages, dated December 11, 2012 (Exhibit Number 2044 filed in interferences 106008, 106013, 106007 on November 18, 2014)
44	USPTO "2014 Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving...Natural Products" ("the March Guidance"), 19 pages, (Exhibit Number 2118 filed in interferences 106,007 and 106,008 on February 17, 2015.



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32986	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

45	USPTO Written Description Training Materials, Revised March 25, 2008, Example 12 (Exhibit Number 1068 filed in interferences 106008, 106007 on December 23, 2014)
46	JWA Clean Copy of Claims and Sequence, as filed in Interference No. 106,007 on August 1, 2014 (Paper 12), 8 pages, (Exhibit Number 2126 filed in interferences 106,007 and 106,008 on February 17, 2015.
47	JWA Clean Copy of Claims and Sequence, as filed in Interference No. 106,007 on August 7, 2014 (Paper 12), 8 pages, (Exhibit Number 2127 filed in interferences 106,007 and 106,008 on February 17, 2015.
48	JWA Motion 1 (For Judgment Under 35 § 112(a)) from Int. No. 106,007 (PN 210), Pages 40, Exhibit Number 1005 filed in Interference 106,013 on February 17, 2015.
49	JWA Motion 1 (For Judgment Under 35 § 112(a)) from Int. No. 106,008 (Doc 213), Pages 38, Exhibit Number 1004 filed in Interference 106,013 on February 17, 2015.
50	JWA submission of teleconference transcript , 28 pages, dated December 12, 2014 (Exhibit Number 2114 filed in interferences 106008 and 106007 on December 12, 2014)

If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

Examiner Signature	/KIMBERLY CHONG/ (10/01/2017)	Date Considered	10/01/2017
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32987	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Doc code: IDS

# 32969

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2016. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number	15705172
	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	AVN-008CN41

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32970	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

1	Valorization Memorandum published by the Dutch Federation of University Medical Centers in March 2009, (University of Western Australia Exhibit 2140, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-33).
2	VAN DEUTEKOM et al., "Antisense-induced exon skipping restores dystrophin expression in DMD patient derived muscle cells," HUMAN MOLECULAR GENETICS Vol. 10, No. 15: 1547-1554 (2001) (Exhibit Number 1084 filed in Interferences 106008, 106007 on December 23, 2014)
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6	van Putten M, et al., "The Effects of Low Levels of Dystrophin on Mouse Muscle Function and Pathology. PLoS ONE 2012;7:e31937, 13 pages
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8	VERMA, Sandeep et al., "Modified Oligonucleotides: Synthesis and Strategy for Users," Annu. Rev. Biochem., Vol. 67:99-134 (1998) (Exhibit Number 1040 filed in interferences 106008, 106007 on November 18, 2014)
9	Vikase Corp. v. Am. Nat'l. Can Co., No. 93-7651, 1996 WL 377054 (N.D. Ill. July 1, 1996), 3 pages (Exhibit Number 2152 filed in interference 106013 on October 29, 2015)
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STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32971	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

12	Wahlestedt et al., "Potent and nontoxic antisense oligonucleotides containing locked nucleic acids," PNAS, Vol. 97, No. 10, pp. 5633-5638 (May, 2000), Exhibit Number 1201 filed in Interferences 106,007 and 106,008 on February 17, 2015.
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14	WANG, Chen-Yen et al., "pH-sensitive immunoliposomes mediate target-cell-specific delivery and controlled expression of a foreign gene in mouse," Proc. Natl. Acad. Sci. USA, Vol. 84:7851-7855 (1987)
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Application Number # 32972	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

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27	WONG, Marisa L. et al., "Real-time PCR for mRNA quantitation," BioTechniques, Vol. 39:75-85 (2005) (Exhibit Number 1066 filed in interferences 106008, 106007 on November 18, 2014)
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32973	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32974	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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**EXAMINER SIGNATURE**

Examiner Signature	/KIMBERLY CHONG/ (10/01/2017)	Date Considered	10/01/2017
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32975	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number	15705172
	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	AVN-008CN41

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32978	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

1	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Responsive Motion 4 (To Add Two New Claims), 65 pages, Patent Interference No. 106,007, (Doc 241), dated December 23, 2014.
2	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Statement Regarding Oral Argument, filed in Patent Interference No. 106,013, April 10, 2015, pages 1-3 (Doc 189).
3	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Opposition 4 (To Not Exclude Evidence), filed in Patent Interference No. 106,007, May 5, 2015, pages 1-22 (Doc 465).
4	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Opposition 4 (To Not Exclude Evidence), filed in Patent Interference No. 106,008, May 5, 2015, pages 1-21 (Doc 473).
5	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Second Supplemental Notice of Real Party in Interest, filed in Patent Interference No. 106,007, May 28, 2015, pages 1-3, (Doc 468)
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7	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Second Supplemental Notice of Real Party in Interest, filed in Patent Interference No. 106013, May 28, 2015, pages 1-3, (Doc 191)
8	University of Western Australia v. Academisch Ziekenhuis Leiden, ACADEMISH ZIEKENHUIS LEIDEN SUPPLEMENTAL NOTICE OF REAL PARTY IN INTEREST, Pages 3, DOC 149, Patent Interference No. 106,013 dated February 23, 2015.
9	University of Western Australia v. Academisch Ziekenhuis Leiden, ACADEMISH ZIEKENHUIS LEIDEN SUPPLEMENTAL NOTICE OF REAL PARTY IN INTEREST, Pages 3, Doc 413, Patent Interference No. 106,0007 dated February 23, 2015.
10	University of Western Australia v. Academisch Ziekenhuis Leiden, ACADEMISH ZIEKENHUIS LEIDEN SUPPLEMENTAL NOTICE OF REAL PARTY IN INTEREST, Pages 3, Doc 421, Patent Interference No. 106,0008 dated February 23, 2015.
11	University of Western Australia v. Academisch Ziekenhuis Leiden, Amendment and Response, US Application No. 11/233,495, Filed 1/22/2014, 8 pages, (Exhibit Number 2117 filed in interferences 106,007 and 106, 008, on February 17, 2015.



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32979	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

12	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Annotated Copy of Claims, Patent Interference No. 106,007, 15 pages, dated August 15, 2014 (Doc 15)
13	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Annotated Copy of Claims, Patent Interference No. 106,008, 14 pages, dated August 21, 2014 (Doc 14)
14	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Annotated Copy of Claims, Patent Interference No. 106,013, 14 pages, dated October 27, 2014 (Doc 16)
15	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Clean Copy of Claims and Sequence, filed in Patent Interference No. 106,013, 5 pages, dated October 15, 2014 (Doc 12)
16	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Corrected Notice of Related Proceedings, Patent Interference No. 106,007, 3 pages, dated August 1, 2014 (Doc 13)
17	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Exhibit List, 10 pages, Patent Interference No. 106,007 dated December 23, 2014 (Doc 240)
18	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL List of Exhibits, 9 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 209)
19	University of Western Australia v. Academisch Ziekenhuis Leiden, Azi List of Exhibits, as of November 18, 2014, 9 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 212)
20	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL List of Proposed Motions, Patent Interference No. 106,007, 6 pages, dated September 10, 2014 (Doc 16)
21	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL List of Proposed Motions, Patent Interference No. 106,008, 8 pages, dated September 10, 2014 (Doc 15)
22	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. sections 102 and 103), 69 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 181)



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32980	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

23	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. sections 102 and 103), 69 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 184)
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25	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 2 (To Deny UWA the Benefit of AU 2004903474), 24 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 29)
26	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 3 (For Judgment of Unpatentability based on Myriad) 20 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 30)
27	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 3 (For Judgment of Unpatentability based on Myriad), 19 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 27)
28	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Notice of Related Proceedings, Patent Interference No. 106,007, 3 pages, dated July 31, 2014 (Doc 6)
29	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Notice of Related Proceedings, Patent Interference No. 106,008, 3 pages, dated August 5, 2014 (Doc 7)
30	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Notice of Related Proceedings, Patent Interference No. 106,013, 3 pages, dated October 15, 2014 (Doc 11)
31	University of Western Australia v. Academisch Ziekenhuis Leiden, Clean Copy of Claims and Sequences, 5 pages, dated August 5, 2014 (Exhibit Number 2047 filed in interferences 106008, 106013, 106007 on November 18, 2014)
32	University of Western Australia v. Academisch Ziekenhuis Leiden, Clean Copy of Claims and Sequences, 5 pages, dated July 31, 2014 (Exhibit Number 2045 filed in interferences 106008, 106013, 106007 on November 18, 2014)
33	University of Western Australia v. Academisch Ziekenhuis Leiden, Clean Copy of Claims and Sequences, 5 pages, dated October 15, 2014 (Exhibit Number 2050 filed in interferences 106008, 106013, 106007 on November 18, 2014)

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32981	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

34	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision - Motions - 37 CFR § 41.125(a), filed in Patent Interference No. 106007, April 29, 2016, pages 1-53 (Doc 472)
35	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision- Motions- 37 CFR§ 41.125(a), filed in Patent Interference No. 106,013, June 22, 2015, pages 1-12 (Doc 192).
36	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision- Priority 37 CFR § 41.125 (a), 18 pages, Patent Interference No. 106,013, (Doc 196), dated September 29, 2015.
37	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision-Rehearing -37 CFR § 41.125(c), filed in Patent Interference No. 106,013, December 29, 2015, pages 1-12 (Doc 202).
38	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Erik Sontheimer dated November 17, 2014, Exhibit 1012 filed in Patent Interference Nos. 106,007 and 106,008, 112 pages, filed November 18, 2014
39	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Interference, Patent Interference No. 106,007, 7 pages, dated July 18, 2014 (Doc 1)
40	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Interference, Patent Interference No. 106,008, 7 pages, dated July 24, 2014 (Doc 1)
41	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Interference, Patent Interference No. 106,013, 8 pages, dated September 29, 2014 (Doc 1)
42	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Matthew J.A. Wood, Patent Interference Nos. 106,007, 106,008 and 106,013, 184 pages, dated November 18, 2014 (Exhibit Number 2081 filed in Interferences 106008, 106013, 106007 on November 18, 2014)
43	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 2, 3 and 4, 3 pages, Patent Interference No. 106,013, (Doc 135), dated January 25, 2015.
44	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 3-4, 4 pages, Patent Interference No. 106,007, (Doc 243), dated January 29, 2015.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32982	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

45	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 3-4, 4 pages, Patent Interference No. 106,008, (Doc 247), dated January 29, 2015.
46	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 3-4, 4 pages, Patent Interference No. 106,013, (Doc 137), dated January 29, 2015.
47	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation Regarding Time Periods 4-6, 4 pages, Patent Interference No. 106,007, dated March 19, 2015 (Doc 416)
48	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation Regarding Time Periods 4-6, 4 pages, Patent Interference No. 106,013, (Doc 151), dated March 19, 2015.
49	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation Regarding Time Periods 4-6, 4 pages, Patent Interference No. 106,008, (Doc 424 ), dated March 19, 2015.
50	University of Western Australia v. Academisch Ziekenhuis Leiden, Judgment-37 CFR § 41.127, 2 pages, Patent Interference No. 106,013, (Doc 197), dated September 29, 2015.

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**EXAMINER SIGNATURE**

Examiner Signature	/KIMBERLY CHONG/ (10/01/2017)	Date Considered	10/01/2017
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 32983	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	Not Yet Assigned
Attorney Docket Number	AVN-008CN41

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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See attached certification statement.

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**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2017-09-22
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/705,172	09/14/2017	Stephen Donald WILTON	AVN-008CN41

**CONFIRMATION NO. 2879**

123147

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**PUBLICATION NOTICE**



\*OC000000096463578\*

**Title:** ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

**Publication No.** US-2018-0002697-A1

**Publication Date:** 01/04/2018

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Dated: January 5, 2018  
Electronic Signature for Amy E. Mandragouras, Esq.: /Amy E. Mandragouras, Esq./

Docket No.: AVN-008CN41  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Stephen Donald Wilton *et al.*

Application No.: 15/705,172

Confirmation No.: 2879

Filed: September 14, 2017

Art Unit: 1674

For: ANTISENSE OLIGONUCLEOTIDES FOR  
INDUCING EXON SKIPPING AND  
METHODS OF USE THEREOF

Examiner: K. Chong

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION UNDER**  
**37 C.F.R. § 1.111**

Dear Sir:

In response to the Office Action dated October 5, 2017 (Paper No. 20171001), please amend the above-identified U.S. patent application as follows:

The **Listing of the Claims** begins on page 2 of this paper.

**Remarks/Arguments** begin on page 3 of this paper.



Application No.: 15/705,172

Docket No.: AVN-008CN41

**LISTING OF THE CLAIMS**

1. **(Canceled)**
2. **(Previously Presented)** An antisense oligonucleotide of 20 to 31 bases comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the target region is within annealing site H53A(+23+47) and annealing site H53A(+39+69), wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195), in which uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, and wherein the antisense oligonucleotide induces exon 53 skipping; or a pharmaceutically acceptable salt thereof.
3. **(Previously Presented)** A pharmaceutical composition comprising: (i) an antisense oligonucleotide of 20 to 31 bases comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the target region is within annealing site H53A(+23+47) and annealing site H53A(+39+69), wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195), in which uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, and wherein the antisense oligonucleotide induces exon 53 skipping, or a pharmaceutically acceptable salt thereof; and (ii) a pharmaceutically acceptable carrier.

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### **REMARKS**

Claims 2 and 3 are pending in the application. Applicants respectfully request reconsideration and withdrawal of the rejections as discussed below. Should the Examiner agree, she is urged to call the undersigned to address any outstanding double patenting rejections to expedite prosecution of this application.

#### ***Claim Rejections - 35 USC § 103***

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being obvious over van Ommen *et al.* (WO 2004/083432) and Koenig *et al.* (Nature 338, 509 - 511 06 April 1989). Applicants respectfully traverse this rejection based on the following remarks.

#### **The Office failed to establish a prima facie case of obviousness**

The Office bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. (MPEP §2142, 9<sup>th</sup> Ed.) “The Federal Circuit has stated that ‘rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’” (*Id.* citing *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006); see also *KSR*, 550 U.S. at 418, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval).)

“Obviousness is a question of law with underlying factual findings, including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the pertinent art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence such as commercial success, long-felt need, and the failure of others.” (*KSR Int’l Co. V. Teleflex, Inc.*, 550 U.S. 398 (2007) citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).) With respect to the third inquiry, to establish a *prima facie* case of obviousness, the Office must identify both a reason why a person of ordinary skill in the art would have combined the prior art elements to arrive at the claimed subject matter, and a reason why one of ordinary skill in the art would have considered the outcome predictable. (*KSR Int’l Co. V. Teleflex, Inc.*, 550 U.S. 398 (2007).)

“In cases involving the patentability of a new chemical compound, *prima facie* obviousness under the third *Graham* factor generally turns on the structural similarities and differences between the claimed compound and the prior art compounds.” According to

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established Federal Circuit precedent, a two-part "lead compound" analysis must be satisfied to establish a *prima facie* case of obviousness. (*Otsuka Pharmaceutical Co. Ltd., v. Sandoz, Inc.*, 678 F.3d 1280 (2012).) To satisfy the lead compound analysis, the Office must establish: (1) that one of ordinary skill in the art would have selected the asserted prior art compound as a lead compound for further development, and (2) that the prior art would have motivated one of ordinary skill in the art to modify the lead compound to make the claimed compound with a reasonable expectation of success. (*Id.* at 1291-1292.)

For the reasons below, neither prong of the two part inquiry has been met in the present case. The first prong is not met because the Office failed to provide a reason why one of ordinary skill in the art would have selected SEQ ID NO: 29 ("h53AON1") of van Ommen et al. as a lead compound. The second prong is not met because, even assuming that one of skill in the art would have selected h53AON1 as a lead compound, the Office failed to provide a reason or motivation to specifically **lengthen** h53AON1 by **nine** additional bases of SEQ ID NO: 195 to arrive at the limitation of claim 1 that the base sequence comprises at least 12 consecutive bases of SEQ ID NO: 195.<sup>1</sup> Moreover, there was a significant level of unpredictability associated with selecting a specific antisense oligonucleotide to induce effective exon skipping of human dystrophin pre-mRNA at the time of the invention, and therefore no reasonable expectation of success.

#### Lead Compound Analysis

*i. The Office failed to provide a reason why a person of ordinary skill in the art would have selected h53AON1 as a lead compound*

A lead compound is "a compound in the prior art that would be most promising to modify in order to improve upon its...activity and obtain a compound with better activity." (*Otsuka Pharmaceutical Co. Ltd., v. Sandoz, Inc.*, at 1291 (citing *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007)).) "[A] reason to select a compound as a lead compound depends on **more than just structural similarity**..." *Bristol-Myers Squibb Co. v. Teva Pharmaceuticals USA, Inc.*, 923 F.Supp.2d 602 at 657 (2013) (citing *Matrix Labs.*, 619 F.3d at 1354; emphasis added). Notably, it has been held that "absent

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<sup>1</sup> Applicants note and further explain below that, contrary to the position of the Office, the skilled artisan must lengthen h53AON1 by nine nucleotides, not two nucleotides, of SEQ ID NO: 195 to achieve the requirement of at least 12 bases of SEQ ID NO: 195 recited by the instant claims.

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a reason or motivation based on such prior art evidence, *mere structural similarity* between a prior art compound and the claimed compound *does not inform the lead compound selection.*" (*Otsuka Pharmaceutical Co. Ltd., v. Sandoz, Inc.*, at 1292 (citing *Daiichi Sankyo Co. v. Matrix Labs., Ltd.*, 619 F.3d 1346, 1354 (Fed. Cir. 2010)); emphasis added.)

The Office has not provided any evidence or reasoning to support the conclusion that a person of ordinary skill in the art would have selected h53AON1 as the lead compound. Instead, the Office simply chooses it as its basis for the alleged obviousness of the claimed subject matter. Thus, its' selection by the Office in the absence of any supporting evidence or reasoning as a lead compound can only be through impermissible hindsight. Accordingly, the Office has not established that a person of ordinary skill in the art would select h53AON1 as the lead compound to modify to arrive at the claimed antisense oligonucleotides. For this reason alone, the claims are not *prima facie* obvious over the cited documents, and the Office should therefore withdraw the rejection.

ii. *The cited art does not motivate a person of ordinary skill in the art to modify h53AON1 to make the claimed antisense oligonucleotides with a reasonable expectation of success*

Even if the Office had established that a person of ordinary skill in the art would have selected h53AON1 as the lead compound, the second prong of the test also has not been met. The second prong of the lead compound analysis requires a determination of whether "the prior art would have supplied one of ordinary skill in the art with a reason or motivation to modify a lead compound with a reasonable expectation of success." (*Otsuka Pharmaceutical Co. Ltd., v. Sandoz, Inc.*, 678 F.3d at 1292 (2012).)

The Office relies on van Ommen et al. as teaching a genus of oligonucleotides 16-50 bases in length that are complementary to, and cause skipping of, exon 53, and selects SEQ ID NO: 29 (h53AON1), which it contends is a 18-mer oligonucleotide having a sequence identical to three nucleotides of SEQ ID NO: 195. The Office contends, "[i]t would have been obvious for one of ordinary skill in the art to make an antisense oligonucleotide of 20-31 bases" using "the sequence of h53AON1 to arrive at an oligonucleotide of 20 nucleotides and having 12 nucleotides of SEQ ID No. 195. . ." by "preparing obvious variants of h53AON1 to try to optimize the activity of the oligonucleotide. . ." using "common and efficient strategies" such as

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synthesizing and testing “longer oligonucleotides containing within them” h53AON1. (*See* Office Action at pages 4-5 (emphasis added).)

Applicants submit that a person of ordinary skill in the art would not have been motivated to modify h53AON1 of van Ommen et al. to arrive at the claimed morpholino antisense oligonucleotides, and certainly not with a reasonable expectation of success. Notably, none of the cited documents would have motivated one of ordinary skill in the art to *increase the length* of the 18-mer h53AON1 to 27 bases 100% complementary to the exon 53 target region +23 to +69 and, let alone select at least 12 consecutive bases of SEQ ID NO: 195 and *thymine bases* in place of uracil bases, and select a *morpholino* chemistry backbone rather than a 2'-O-methyl phosphorothioate ("2'-O-Me-PS").<sup>2</sup>

Importantly, Applicants respectfully point out that the Office’s proposed strategy for modification of h53AON1 by lengthening it by only two bases would not result in an antisense oligonucleotide within the scope of the instant claims. To illustrate this point, Applicants provide the following alignment of h53AON1 (line 2) to SEQ ID NO: 195 (line 1).

1.	<u>CUGAAGGUGUUCUUGUACUUCAUCC</u>	SEQ ID NO: 195
2.	CUGUUGCCUCCGGUUC <u>UG</u>	h53AON1
3.	CUGUUGCCUCCGGUUC <u>UGAA</u>	h53AON1+2 bases = 20mer
4.	CUGUUGCCUCCGGUUC <u>CUGAAGGUGUUC</u>	h53AON1+9 bases = 27mer

As can be seen from above and acknowledged by the Office, h53AON1 comprises only three consecutive bases of SEQ ID NO: 195 indicated in the underlined portion of lines 1 and 2. Addition of two additional consecutive bases to h53AON1 as proposed by the Office results in a 20mer that is within the claimed length range, but such a 20mer would only comprise five consecutive bases of SEQ ID NO: 195 as illustrated in line 3 – not at least 12 consecutive bases of SEQ ID NO: 195 as required by the claims. Applicants note that to achieve an antisense oligonucleotide of the instant claims comprising, *inter alia*, at least 12 bases of SEQ ID NO: 195, the skilled artisan would need to, *inter alia*, lengthen h53AON1 by 9 bases as illustrated in the underlined portion of line 4 above. Meaning, simply lengthening h53AON1 by two bases as suggested by the Office would clearly not result in the claim requirement of at least 12 bases of

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<sup>2</sup> Nor can it be found that the claimed invention would have been "obvious to try" as there are *not* a "*finite number of identified, predictable solutions*" such that one ordinarily skilled in the art could have pursued known potential solutions with a reasonable expectation of success. (*Examination Guidelines Update: Developments in the Obviousness Inquiry after KSR v. Teleflex*, issued by the United States Patent and Trademark Office (Federal Register, Vol. 75, No. 169: 53643, September 1, 2010); emphasis added.)

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SEQ ID NO: 195. Applicants base the remainder of the response based on modifying h53AON1 by, *inter alia*, adding 9 consecutive bases of SEQ ID NO: 195.

With regard to van Ommen et al., it cannot be said that there were a "finite number" of known, predictable solutions to the problem of designing a more efficient exon skipping antisense oligonucleotide with a reasonable expectation of success. In fact, van Ommen et al. suggest a wide variety of modifications to the antisense oligonucleotide structure with little specificity as to any individual oligonucleotide in the following:

[t]he complementary oligonucleotide generated through a method of the invention is preferably complementary to a consecutive part of between **16 and 50 nucleotides** of the exon RNA. **Different types of nucleic acid may be used** to generate the oligonucleotide. Preferably, the oligonucleotide comprises RNA, as RNA/RNA hybrids are very stable. Since one of the aims of the exon skipping technique is to direct splicing in subjects, it is preferred that the oligonucleotide RNA comprises a **modification providing the RNA with an additional property**, for instance, resistance to endonucleases and RNaseH, additional hybridization strength, increased stability (for instance, in a bodily fluid), increased or decreased flexibility, reduced toxicity, increased intracellular transport, and/or tissue-specificity, etc. Preferably, the modification comprises a 2'-O-methyl-phosphorothioate oligoribonucleotide modification.

With the advent of **nucleic acid-mimicking technology**, it has become possible to generate molecules that have a similar, preferably the same, hybridization characteristics, in kind, not necessarily in amount, as nucleic acid itself. Such equivalents are, of course, also part of the invention. **Examples of such mimics** equivalents are **peptide nucleic acid, locked nucleic acid and/or a morpholino phosphorodiamidate**. . . . **Hybrids between one or more of the equivalents among each other and/or together** with nucleic acid are, of course, also part of the invention. In a preferred embodiment, an equivalent comprises locked nucleic acid, as locked nucleic acid displays a higher target affinity and reduced toxicity and, therefore, shows a higher efficiency of exon skipping. (van Ommen et al. page 9, line 28 to page 11, line 2; emphasis added.)

van Ommen et al. also teach that "[i]t is thus not absolutely required that all the bases in the region of complementarity are capable of pairing with bases in the opposing strand... *[m]ismatches may to some extent be allowed.*" (van Ommen et al. at page 3, ll. 3-8; emphasis added.) van Ommen et al. does not require that additional bases added to the antisense oligonucleotide be complementary to exon 53. *Id.*

Thus, there are a tremendous number of possible solutions to modify h53AON1 based on the length and position of "16-50 bases," mismatches, and many possible variations at any of three "substituents" (*i.e.*, nucleobase, ribose ring and phosphate linkage). Even if one focuses on



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the nucleobase sequence, assumes the chemical backbone and internucleotide linkages are unmodified, and limits the number of possible bases to those found in RNA, as shown in h53AON1, adding a single nucleobase to a 18-mer yields 8 possible sequence combinations (A, C, G, or U added before or after the 18-mer.)<sup>3</sup> Adding two nucleobases yields 64 possible combinations. Adding three nucleobases yields 256 combinations. Adding 9 nucleobases to obtain a 27-mer yields 2,621,440 possible combinations. And, adding 32 nucleobases to obtain a 50-mer yields 608,742,554,432,415,200,000 possible combinations.

Of course, this significantly *underestimates* the number of possible nucleobase combinations because van Ommen et al. specify "different types of nucleic acid," and is not limited to the "natural" bases A, C, G, and U found in RNA, but includes other naturally-occurring and non-naturally occurring nucleobases such as inosine, hypoxanthine, xanthine, and many others. Different types of nucleic acid also include nucleotide analogs and chemical modifications to the backbone, as all of the working examples by van Ommen et al. use 2'-O-Me-PS oligoribonucleotide modifications. Different types of nucleic acid also include "mimetics" such as peptide nucleic acids, locked nucleic acid, and morpholino phosphorodiamidates. (van Ommen et al. at page 10, ll. 11-16.) Given the incredibly large number of modifications to h53AON1 that are taught by the cited documents the only way to start from h53AON1 and modify it to arrive at the claimed antisense oligonucleotide is by the application of hindsight.

There is also no reason or motivation to specifically *increase* the length of h53AON1 as there is no teaching in van Ommen et al. with respect to the effects on exon skipping of *lengthening* (or shortening) an antisense oligonucleotide. In fact, as shown in Table 2, all of the antisense oligonucleotides with exon skipping activity are *15-24 bases in length*, and all but 3 of those are between *17 and 20 bases*, almost two thirds are either *19 or 20 bases*, and *none are 25 bases in length*. (van Ommen et al. Table 2 at page 48.) As the vast majority of the antisense oligonucleotides tested by van Ommen et al. in Table 2 are *20 bases or less* (25/30), one of ordinary skill in the art would have no reason or motivation to lengthen h53AON1 at all. In fact, one skilled in the art would be equally motivated to shorten h53AON1, as almost two thirds of

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<sup>3</sup> Assuming only the four RNA nucleobases, the number of nucleobase combinations for a particular length AON can be calculated by this formula, where "n" equals the number of bases being added to the chain:  $(4^n) \times (n+1)$ . This is because each additional nucleotide can be added to either end of SEQ ID NO: 29.



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the antisense oligonucleotides are either 19 or 20 bases, and the shortest antisense oligonucleotide with activity in Table 2 is 15 bases (h46AON4b).

Moreover, the Office failed to provide a reason why the skilled artisan would lengthen h53AON1. Instead, the Office merely concludes the skilled artisan would “prepare obvious variants of h53AON1 to try to optimize the activity of the oligonucleotide” and that the skilled artisan would “try” to enhance activity by “a common and efficient strategy” of synthesizing and testing “longer oligonucleotides containing within them the sequence known to have the desired activity.” Office Action at pages 4-5. The Office overlooks the fact that in Table 2 the only other antisense oligonucleotide made and tested by van Ommen et al. is h53AON2, and this antisense oligonucleotide – like h53AON1 – is an 18mer. Applicants respectfully point out that “[a] particular parameter must first be *recognized* as a *result-effective variable*, i.e., a variable which achieves a *recognized* result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.” M.P.E.P. 2144.05(II)(B) (emphasis added); see also *In re Antonie*, 559 F.2d 618, 195 U.S.P.Q. 6 (CCPA 1977).

In the present case, the Office failed to satisfy its burden of providing evidence that oligonucleotide length was recognized in the prior art as a result effective variable for exon 53 skipping and activity in treatment for DMD. See *id.* Absent such evidence of recognition as a “result-effective variable[.]” it is not, therefore, routine optimization “within the skill of the artisan” to vary the length of an oligonucleotide to optimize exon 53 skipping and activity in the treatment of DMD. See M.P.E.P. 2144.05(II)(B); *In re Antonie*, 559 F.2d 618, 620, 195 U.S.P.Q. 6, 8-9 (C.C.P.A. 1977) (optimization of a parameter not recognized as a result-effective variable is an exception to the rule that “discovery of an optimum value of a variable in a known process is normally obvious”). Thus, the Office’s proffered rationale of routine optimization by lengthening h53AON1 does not apply.

Given the length of 16-50 bases and the many possible variations in nucleobase and backbone chemistry taught by van Ommen et al., there is *not* a “finite number” of known, predictable solutions to modifying h53AON1 such that one of ordinary skill in the art would arrive at the claimed morpholino antisense oligonucleotides of 20 to 31 bases having a base sequence 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the target region is within annealing site H53A(+23+47) and annealing site H53A(+39+69), and having at least 12 consecutive bases of SEQ ID NO: 195 in which uracil bases are thymine bases, with a reasonable expectation of success. In fact, there is

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absolutely nothing in van Ommen et al. about selecting a morpholino chemistry backbone and thymine bases, rather than uracil bases.

iii. **High level of unpredictability in the field with no reasonable expectation of success**

Even assuming, *arguendo*, that one of ordinary skill would have selected h53AON1 of van Ommen et al. as a lead compound and would have been motivated to modify it in the particular way necessary to arrive at the subject matter of the claims, there would be no reasonable expectation of success because at the time the instant invention was made, there was a significant level of unpredictability associated with selecting specific antisense oligonucleotide sequences to induce effective dystrophin exon skipping. For example, the specification as originally filed notes that the size or length of an antisense oligonucleotide is not predictive of its efficacy (specification at page 21, lines 11-12). In addition, Applicants have found that there is no standard motif that can be blocked or masked by antisense molecules to redirect splicing (specification at page 21, lines 18-20). Applicants submit that the cited art does not provide sufficient guidance to arrive at the claimed subject matter considering the high level of unpredictability in the art.

Applicants refer the Office to van Deutekom *et al.* (2003) Nature Reviews, 4:774-783 (“van Deutekom Review”; submitted in an Information Disclosure Statement on September 22, 2017). This article is a review that generally discloses exon skipping in the dystrophin gene. The van Deutekom Review notes that interfering with exon selection for inclusion before splicing is “a process that is ***not yet well understood***” (page 780, col. 1, lines 1-3, emphasis added).

Applicants also refer the Office to U.S. Patent Application Publication No. 2006/0147952 to van Ommen et al. (the ‘952 Publication) describe an approach in which “AONs were ***empirically analyzed*** for the induction of exon skipping.” (‘952 Publication at [0051]; emphasis added.) Such an approach relies on experience or observation and provides no indication as to what parameters are critical for the design of exon skipping antisense. As each antisense oligonucleotide must be empirically analyzed, the results are ***unpredictable*** as reported in Table 2 of the ‘952 Publication:

[t]heir different lengths and G/C contents (%) ***did not correlate to their effectivity in exon skipping*** (1, induced skipping, 2, no skipping). The AONs were directed to purine

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(A/G)-rich sequences as indicated by their (antisense) U/C content (%). Skipping of the target exons resulted in either an in-frame (IF) or out-of-frame (OF) transcript. (van Ommen et al. [0153], Table 2, footnote *a*; emphasis added.)

Additional evidence of unpredictability is found by analyzing the antisense sequences in Table 2 of the '952 Publication. For example, the two antisense oligonucleotides designed to induce skipping of exon 2 have overlapping nucleotide sequences:

h2AON1	cccauuuugugaauguuuucuuuu
h2AON2	uugugcauuuacccaauuugug

Despite the overlap in sequence, h2AON1 purportedly induced skipping, while h2AON2 did *not*. ('952 Publication at Table 2.) And yet for another pair of overlapping AONs, both members of the pair did purportedly induce skipping:

h29AON1	uauccucugaaugucgcauc
h29AON2	gguaauccucugaaugucgc

There is no explanation in the '952 Publication for these disparate results.

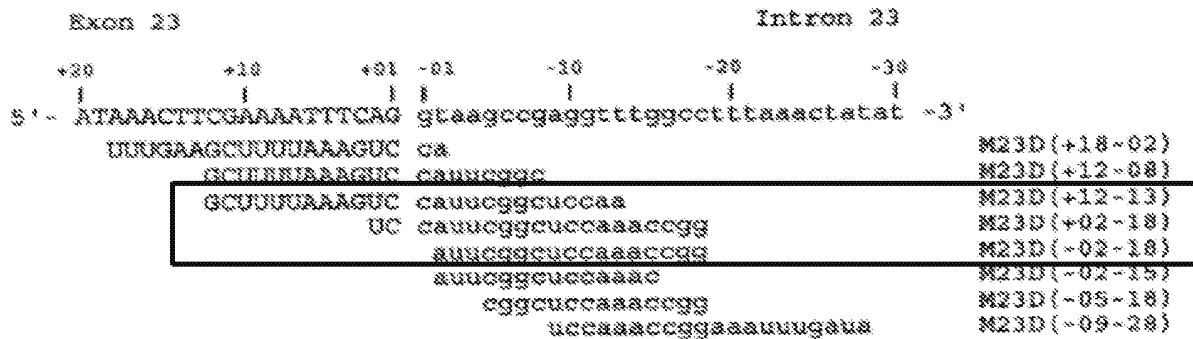
Much of the data in Table 2 of the '952 Publication was published in 2002 by Aartsma-Rus et al. (Neuromuscular Disorders, 12:S71-S77 (2002) ("Aartsma-Rus (2002)"; submitted in an Information Disclosure Statement on September 22, 2017). Aartsma-Rus (2002) discloses two specific oligonucleotides directed at dystrophin exon 53 and notes that there is *no correlation* between the length or sequence of the oligonucleotide and its effectiveness at inducing exon skipping. (Aartsma-Rus (2002) at page S76, col. 1, lines 43-45.) Still further, Aartsma-Rus (2002) teaches that *significant experimentation is required* to arrive at specific oligonucleotides, noting that "[w]e therefore have *no insight* into the actual position of the targeted sequence within the completely folded RNA structure. Its accessibility, and thus the effectivity of any designed AON, will therefore have to be tested *empirically* in the cells, as was done in this study." (Aartsma-Rus (2002) at page S76, col. 1, lines 4-6; emphasis added.)

Another study, co-authored by one of the Applicants, examined skipping of exon 23 from the mouse DMD gene by RT-PCR following transfection with a series of overlapping 2'-Me-O-PS AONs, as shown in the following figure. Of the antisense oligonucleotides tested, only M23D(+12-13), M23D(+02-18), and M23D(-02-18) were effective in inducing detectable exon

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skipping. (Mann et al., J. Gene Med., 4(6): 644-654 (2002); submitted in an Information Disclosure Statement on September 22, 2017.)



(Mann et al. at 646.) Notably, the *shorter* antisense oligonucleotide M23D(-02-18), which is only **17 nucleotides** in length, was particularly efficient at inducing skipping and was reported to induce exon skipping at concentrations as low as 5 nM. The authors concluded that they could improve “the efficiency of the technique” by “*reduc[ing] the size* and the effective dose of the AO[N]s” examined. (Mann et al. at 644; emphasis added.)

Similar examples of unpredictability were reported by van Ommen et al. and other investigators at or near the date of Applicants' invention. In a 2005 publication the same design rationale described by van Ommen and coworkers was applied again. (Aartsma-Rus et al. Oligonucleotides, 15(4): 284-297 (2005) ("Aartsma-Rus (2005)"; submitted in an Information Disclosure Statement on September 22, 2017.) Table 1 of Aartsma-Rus (2005) provides the sequences of the antisense oligonucleotides and whether or not they induced skipping. (Aartsma-Rus (2005) at 285, first and second columns.) The following pairs of antisense oligonucleotides are found in the Table (+ and – refer to skipping ability):

h29AON10	guaguucccuccaaccg	–
h29AON11	cauguaguucccucc	+
h43AON2	uuguuaacuuuuucccauu <sup>4</sup>	+

<sup>4</sup> There is a discrepancy between the disclosure of Aartsma-Rus (2005) and the sequence as shown by van Ommen et al. In the 2005 publication, the sequence is shown as uuguuaacuuuuucccauu, while in Table 2

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h43AON3	uguuaacuuuuucccauugg	-
h46AON8	gcuuuucuuuuaguugcugc	++
h46AON9	uuaguugcugcucuu	-
h48AON3	ggucuuuuauuugagcuuc	-
h48AON7	uuuauuugagcuucaaauuu	+

It is evident from these results that applying the design rationale described by van Ommen et al. is a hit-or-miss proposition in terms of whether any given antisense oligonucleotide will be capable of inducing skipping, *even in situations where the antisense oligonucleotides are very similar to each other in terms of nucleotide sequence, and other variables concerning the chemical backbone are fixed*. All of the antisense oligonucleotides described in the study “contain 2’-O-methyl RNA and full-length phosphorothioate (PS) backbones.” (Aartsma-Rus (2005) at 285.) None of the antisense oligonucleotides disclosed were longer than 24 nucleotides, and the majority of the antisense oligonucleotides were 20 nucleotides in length or shorter. (Aartsma-Rus at Table 1.) None of these antisense oligonucleotides include non-natural bases. Given the common chemical modifications of these antisense oligonucleotides, the data reported in this paper demonstrates the unpredictable impact that length and nucleotide composition make with respect to efficiency in inducing exon skipping.

The recognition of the lack of predictability in the field of exon skipping continued beyond 2005. A 2007 paper co-authored by van Ommen co-inventors Aartsma-Rus and van Deutekom states that “several years after the first attempts at dystrophin exon skipping with AOs [antisense oligonucleotides], *there are still no clear rules to guide investigators in their design*, and in mouse and human muscle cells *in vitro there is great variability for different targets and exons*.” (Arechavala-Gomez et al. Hum. Gene Ther., 18(9): 798-810, 807 (2007); submitted in an Information Disclosure Statement on September 22, 2017; emphasis added.)

And again in 2009 van Ommen and co-workers wrote that while existing software programs can facilitate design, “in general *a trial and error procedure* is still involved to

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of van Ommen et al. it shown as above having a sequence of "ccc" toward the 3’ end of the AON. It is assumed the latter is correct as it corresponds to the sequence of h43AON3.

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identify potent AONs.” (Aartsma-Rus et al., *Mol. Ther.*, 17(3):548-553 (2009) at 548; submitted in an Information Disclosure Statement on September 22, 2017; emphasis added.)

Evidence that selecting specific antisense oligonucleotide sequences to induce effective dystrophin exon skipping remains an unpredictable exercise is also found in a 2011 publication by Wu *et al.* (2011) *PLoS One*, 6(5): e19906 (submitted in an Information Disclosure Statement on September 22, 2017). Although Wu *et al.* is evidence developed after the instant filing date, the level of unpredictability in the art directly relates to whether the results obtained with any specific species would be unexpected and courts have held that it is not “improper to conduct additional experiments and provide later-obtained data in support of patent validity.” *Knoll Pharm. Co., Inc. v. Teva Pharms. USA, Inc.*, 367 F.3d 1381, 1385 (Fed. Cir. 2004). Evidence of the lack of predictability of in the field is relevant to the non-obviousness of the claimed antisense oligonucleotides over the cited art.

Wu *et al.* describe a systematic approach for identifying antisense oligonucleotides of high efficacy in inducing dystrophin exon skipping. Wu *et al.* designed 25 antisense oligonucleotides (AOs) to cover more than two thirds of exon 50 of the human dystrophin gene and the two flanking intron sequences. Wu *et al.* determined the efficiency of AO-induced skipping of exon 50 by comparing the activity of a series of AOs. Table 1 on page 4 of the publication summarizes all the AOs tested, including both 2'-O-methyl phosphorothioate and morpholino antisense oligonucleotides, as well as their reported activity in two assays. The exon skipping effect was determined using both a GFP reporter cell line with GFP expression coupled to exon 50 skipping and normal human myoblasts.

As shown in Table 1, Wu *et al.* tested AOs having a common 5' or 3' termini, but varied in length. Shown below is an excerpt from Table 1 of Wu *et al.*

hES0 AO2PS	--19--1	5'-CUUUAAACAGAAAAGCAUAC-3'	19 bp	-	-	N/D
hES0 AO3PS	--19+1	5'-UCUUUAAACAGAAAAGCAUAC-3'	20 bp	-	-	N/D
hES0 AO4PS	--19+3	5'-CCUCUUUAAACAGAAAAGCAUAC-3'	22 bp	4%	3%	N/D
hES0 AO5PS	--19+8	5'-AACUCCUCUUUAAACAGAAAAGCAUAC-3'	27 bp	21%	29%	N/D
hES0 AO6PS	--19+13	5'-CUUCUAAACUCCUCUUUAAACAGAAAAGCAUAC-3'	32 bp	3%	<1%	N/D

Each of these AOs target exon 50 starting at position (-19) and ending at position (-1), (+1), (+3), (+8) and (+13), respectively, and the oligonucleotides overlap at the 3' end. These AOs varied in length from 19 to 32 bases and the data shows that increasing AO length does not



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necessarily increase exon skipping activity and there is no reasonable expectation of success in increasing AO length to obtain increased exon skipping activity. For example, the 19- and 20-mer AOs hE50 AO2PS and hE50AO3PS were inactive. Increasing the length to 22 and 27 bases (hE50 AO4PS and hE50 AO5PS, respectively) resulted in increased activity, but a further increase to 32 bases (hE50 AO6PS) decreased activity significantly. Specifically, hE50 AO5PS is 5 nucleotides longer than hE50 AO4PS, but the level of GFP of hE50 AO5PS is 17% higher with respect to GFP assay and 26% higher with respect to human myoblasts. hE50 AO5PS is 5 nucleotides shorter than hE50 AO6PS, but the level of GFP of hE50 AO5PS is 18% higher with respect to GFP and 28% higher with respect to human myoblasts.

The data provided in Table 1 also demonstrate that when hE50 AO4PS (-19+3) was extended five nucleotides in length to hE50A AO5PS (-19+8), activity was increased. Notably, however, the addition of yet another five nucleotides to hE50 AO6PS (-19+13) essentially eliminated the activity.

In yet another example, a relatively short oligonucleotide (hE50 AO19PS; +97-5) at the 3' end of the exon showed low activity (3%) with respect to GFP, and activity did not increase when the oligonucleotide was lengthened by five or nine nucleotides at the 5' end (hE50 AO20PS and hE50 AO21PS, respectively) or by five nucleotides in the 3' direction (hE50 AO16PS). These four antisense oligonucleotides showed no activity in the human myoblasts. Thus, Wu *et al.* demonstrate that increasing or decreasing AO length results in unpredictable effects on exon skipping.

Importantly, the Patent Trial and Appeal Board (PTAB) in Interference No. 106,007 (“the ‘007 interference”) concerning exon 53 antisense oligonucleotides for DMD held that the field of antisense oligonucleotides for exon skipping for DMD was unpredictable at the time the instant application was filed. Its decision was based on the foregoing evidence and expert testimony. *See* Decision on Motions in Interference No. 106,007 (exon 53) dated May 12, 2016 (decision final upon withdrawal of CAFC Appeal No. 2016-2262; Decision on Motions previously submitted in an Information Disclosure Statement on September 22, 2017). Specifically, the PTAB determined that sequence length of antisense oligonucleotides that would maintain exon skipping was substantially unpredictable at the time US Application No. 11/233,495 was filed by Academisch Ziekenhuis Leiden (“AZL”). *See id.* at page 5, line 26 to page 6, line 3. Applicants note that the ‘495 application claims priority to the van Ommen *et al.* PCT application presently cited by the Office. In its Decision, the PTAB



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considered the foregoing evidence as representative of the state of the art with Exhibits 2010 and 2015 in Interference 106,007 corresponding to Aartsma-Rus and Wu *et al.*, submitted herewith as Appendices A and C, respectively. Unpredictability in this art was determined by the PTAB to have existed at the time of the instant invention (and years afterwards).

Upon consideration of this evidence, the PTAB stated “[t]he evidence indicates that at the time AZL filed its application, the identification of AONs that will cause exon skipping was generally thought to be unpredictable. One of the significant factors causing that unpredictability is the effect of the number of nucleobases present in the AON.” (Decision on Motions at page 17 (emphasis added)). In particular, the relationship between length of a base sequence and the ability of an antisense oligonucleotide to induce exon skipping was considered by the PTAB.

Despite the unpredictability in the art, the PTAB found obvious a 20mer AON based on SEQ ID NO: 193 over a completely overlapping 18mer (h53AON1). In this particular circumstance, the PTAB found that “a degree of exon skipping capability would likely be maintained due to a change in a *small number of complementary nucleobases* of an AON known to cause skipping” and, therefore, concluded “[i]t would have been obvious, for example, to add the *two* complementary nucleobases dictated by the known sequence of exon 53 to either end of h53AON1 with a reasonable expectation that the resultant 20 base AON would cause exon skipping.” *Id.* at pages 41-42 (emphasis added).

In contrast to the narrow issue considered by the PTAB described above, the PTAB does not support a determination of obviousness of the instant claims. The PTAB’s determination of unpredictability still applies. And to arrive at the instantly claimed antisense oligonucleotides, a person of ordinary skill would have to modify h53AON1 by adding at least *9 bases* (and would have to do so with a reasonably expectation of success). Such a modification in length cannot be said to be predictable under the Decision in the ‘007 interference. Accordingly, it would not have been obvious to extend h53AON1 by 9 bases at least because of the highly degree of unpredictability discussed above, and the Office failed to provide evidence to the contrary.

Furthermore, similar to the Office’s assertion, AZL argued that upon identification of h53AON1, “one skilled in the art would have investigated extended complementary sequences with the expectation that the longer sequences would bind and cause skipping.” *Id.* The PTAB did not find this argument persuasive at least because AZL failed to provide any

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evidence to support the basis for this expectation. *Id.* at page 18. Like AZL, the Office failed to provide evidence to support this argument. *See* Office Action at page 5. Accordingly, Applicants urge the Office to adopt the PTAB's determination of unpredictability in the field of exon skipping for DMD.

In summary, the van Deutekom Review, Aartsma-Rus and Wu *et al.* references, along with the Decision on Motions in the '007 interference, serve to illustrate the unpredictability associated with selecting *specific* antisense oligonucleotides that are effective for inducing skipping of dystrophin exons. Accordingly, the Office failed to establish a *prima facie* case of obviousness with respect to the predictability of the outcome in combining teachings of van Ommen *et al.* and Koenig *et al.* in the manner proposed to arrive at the claimed invention.

In view of the preceding remarks, Applicants submit that the Office failed to establish a *prima facie* case of obviousness based on the cited art. As such, Applicants respectfully request reconsideration and withdrawal of this obviousness rejection.

#### ***Double Patenting***

Claims 2 and 3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 8,455,636. Applicants respectfully traverse this rejection.

The Office asserts "the instant claims and the claims of the patent are drawn to antisense oligonucleotides having at least 17 consecutive bases of SEQ ID No. 193." Office Action at page 6. However, Applicants note the instant claims are drawn to antisense oligonucleotide having 20-31 bases and comprising at least 12 consecutive bases of SEQ ID NO: 195. Moreover, the '636 patent is directed to an antisense oligonucleotide comprising 20-50 bases and at least 20 consecutive bases of SEQ ID NO: 193. As such, Applicants point out that there is only a 2 base overlap between SEQ ID NOs: 193 of the '636 Patent and SEQ ID NO: 195 of the instant claims. Accordingly, Applicants respectfully request that the Office consider withdrawing the instant rejection in view of these facts and the foregoing remarks.

Claims 2 and 3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 8,232,384. Applicants respectfully request clarification of this rejection. Specifically, The Office asserts

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“the instant claims and the claims of the patent are drawn to antisense oligonucleotides having at least 17 consecutive bases of SEQ ID No. 193.” Office Action at page 7. However, Applicants note the instant claims are drawn to antisense oligonucleotide having 21-30 bases and comprising at least 12 consecutive bases of SEQ ID NO: 195. Moreover, the ‘384 patent is directed to an antisense oligonucleotide *consisting* of SEQ ID NO: 195. Accordingly, Applicants respectfully request clarification.

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**CONCLUSION**

In view of the foregoing, Applicants respectfully submit that the pending claims are in condition for allowance. If a telephone conversation with Applicants' attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 217-4626. If a fee is due with this submission, please charge our Deposit Account No. 12-0080 under Order No. AVN-008CN41, from which the undersigned is authorized to draw

Dated: January 5, 2018

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**Electronic Acknowledgement Receipt**

<b>EFS ID:</b>	31418918
<b>Application Number:</b>	15705172
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	2879
<b>Title of Invention:</b>	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF
<b>First Named Inventor/Applicant Name:</b>	Stephen Donald WILTON
<b>Customer Number:</b>	123147
<b>Filer:</b>	Amy E. Mandragouras
<b>Filer Authorized By:</b>	
<b>Attorney Docket Number:</b>	AVN-008CN41
<b>Receipt Date:</b>	05-JAN-2018
<b>Filing Date:</b>	14-SEP-2017
<b>Time Stamp:</b>	16:01:20
<b>Application Type:</b>	Utility under 35 USC 111(a)

**Payment information:**

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**File Listing:**

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Req. Reconsideration-After Non-Final Reject	2018_01_05_Response_to_Office_Action_AVN-008CN41.pdf	947608 e3375c8063d69fd5d3ec803dd094e542d6c09b18	no	19

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If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc code: IDS

# 33007

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number		15705172
	Filing Date		2017-09-14
	First Named Inventor		Stephen Donald WILTON
	Art Unit		1674
	Examiner Name	K. Chong	
	Attorney Docket Number		AVN-008CN41

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	2	20170283799	A1	2017-10-05	KAYE		
	3	20170292125	A1	2017-10-12	SAZANI et al.		
	4	20170369875	A1	2017-12-28	BESTWICK et al.		
	5	20170369876	A1	2017-12-28	BESTWICK et al.		



Application Number  
# 33008

15/05172

Filing Date

2017-09-14

First Named Inventor

Stephen Donald WILTON

Art Unit

1674

Examiner Name

K. Chong

Attorney Docket Number

AVN-008CN41

**INFORMATION DISCLOSURE  
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**FOREIGN PATENT DOCUMENTS**

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Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup>	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1							

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**NON-PATENT LITERATURE DOCUMENTS**

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1	European Decision of the Opposition Division, European Application No. 10004274.6, dated December 19, 2017, 23 pages.	
	2	Extended European Search Report, EP 16172354.9, dated January 23, 2017, 7 pages.	
	3	Extended European Search Report, EP 17159328.8, dated September 5, 2017, 10 pages.	
	4	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Filing Priority Statement, 2 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 215)	

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**EXAMINER SIGNATURE**

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	K. Chong
Attorney Docket Number	AVN-008CN41

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number # 33010	15/05172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	K. Chong
Attorney Docket Number	AVN-008CN41

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

- ☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☒ A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2018-01-05
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with 37 CFR § 1.6(a)(4).

Dated: January 5, 2018  
Electronic Signature for Amy E. Mandragouras, Esq.: /Amy E. Mandragouras, Esq./

Docket No.: AVN-008CN41  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

---

In re Patent Application of:  
Stephen Donald Wilton *et al.*

Application No.: 15/705,172

Confirmation No.: 2879

Filed: September 14, 2017

Art Unit: 1674

For: ANTISENSE OLIGONUCLEOTIDES FOR  
INDUCING EXON SKIPPING AND  
METHODS OF USE THEREOF

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Examiner: K. Chong

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (SIDS)**

Dear Sir:

In compliance with 37 C.F.R. § 1.56, 1.97 and 1.98, the attention of the U.S. Patent and Trademark Office is hereby directed to the documents listed on the attached PTO/SB/08. In accordance with 37 C.F.R. § 1.98(a)(2)(i)-(iv), Applicant submits herewith copies of the non-patent literature references, but has not included copies of U.S. patents and/or U.S. patent applications.

It is respectfully requested that the documents listed on the PTO/SB/08 be expressly considered by the Examiner during the prosecution of this application, and that the documents be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Application No.: 15/705,172 (Information Disclosure Statement)

Docket No.: AVN-008CN41

Applicant calls to the attention of the Examiner the following Applications and provides copies of Office Actions cited therein, as well as, copies of Office Actions from Applications previously made of record:

<b>Applications</b>				
<i>Examiner's Initials</i>	<i>Serial No.</i>	<i>Filing Date</i>	<i>First Named Inventor</i>	<i>Docket No.</i>
	15/349,778	11-11-2016	Peter SAZANI	AVN-009DVCN6
	15/420,823	01-31-2017	R.K. BESTWICK	AVN-010PCCN2
	15/359,152	11-22-2016	E.M. KAYE	AVN-012ACN
	15/422,127	February 1, 2017	R.K. BESTWICK	AVN-013BCN
	15/417,401	01-27-2017	R.K. BESTWICK	AVN-017CN

<b>Office Actions (copies enclosed)</b>			
<i>Examiner's Initials</i>	<i>Serial No.</i>	<i>Date Mailed from USPTO</i>	<i>Examiner</i>
	15/422,127	November 27, 2017	D.H. Shin
	15/417,401	October 12, 2017	D.H. Shin
	15/359,152	January 5, 2018	E. Poliakova-Georgan
	15/420,823	November 2, 2017	A. Hudson Bowman
	14/776,533	November 16, 2017	D. Shin

The Examiner is requested to review the file histories of these applications, including cited references, Office Actions, Responses, etc., and is asked to contact Applicant's Attorney if the Examiner would like the Applicant to supply copies of any or all of the information included in any of these applications. For any of these applications, if Applicant's Attorney is not contacted by the Examiner with such a request, then it will be concluded that the Examiner has reviewed or will review the file content of these applications.

Applicant respectfully requests that the Examiner initial the blank columns next to the cited Applications and Office Actions, to indicate that the information has been considered by the Examiner. Alternatively, Applicant requests that the Examiner insert the phrase, "All references considered except where lined through," on each page of the Information Disclosure Statement, along with the Examiner's initials.

Application No.: 15/705,172 (Information Disclosure Statement)

Docket No.: AVN-008CN41

The filing of this Information Disclosure Statement is not to be interpreted as a representation that the cited documents are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any documents herein be construed *per se* as a representation that such document is prior art. Moreover, Applicant understands the Examiner will make an independent evaluation of the cited documents.

This Information Disclosure Statement is filed after the mailing date of a first Office Action on the merits, but before the mailing date of any of a Final Action under 37 C.F.R. § 1.113, a Notice of Allowance under 37 C.F.R. § 1.311 or an action that otherwise closes prosecution in this application (37 C.F.R. § 1.97(c)).

Please charge our Deposit Account No. 12-0080 in the amount of \$90.00 covering the fee set forth in 37 C.F.R. § 1.17(p). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 12-0080, under Order No. AVN-008CN41.

Dated: January 5, 2018

Respectfully submitted,

Electronic signature: /Amy E. Mandragouras, Esq./  
Amy E. Mandragouras, Esq.  
Registration No.: 36,207  
NELSON MULLINS RILEY & SCARBOROUGH LLP  
One Post Office Square  
Boston, Massachusetts 02109-2127  
(617) 217-4626  
(617) 217-4699 (Fax)  
Attorney/Agent For Applicant



Electronic Patent Application Fee Transmittal				
<b>Application Number:</b>		15705172		
<b>Filing Date:</b>		14-Sep-2017		
<b>Title of Invention:</b>		ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF		
<b>First Named Inventor/Applicant Name:</b>		Stephen Donald WILTON		
<b>Filer:</b>		Amy E. Mandragouras		
<b>Attorney Docket Number:</b>		AVN-008CN41		
Filed as Small Entity				
<b>Filing Fees for Utility under 35 USC 111(a)</b>				
<b>Description</b>	<b>Fee Code</b>	<b>Quantity</b>	<b>Amount</b>	<b>Sub-Total in USD(\$)</b>
<b>Basic Filing:</b>				
<b>Pages:</b>				
<b>Claims:</b>				
<b>Miscellaneous-Filing:</b>				
<b>Petition:</b>				
<b>Patent-Appeals-and-Interference:</b>				
<b>Post-Allowance-and-Post-Issuance:</b>				
<b>Extension-of-Time:</b>				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Miscellaneous:</b>				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	90	90
<b>Total in USD (\$)</b>				<b>90</b>

**Electronic Acknowledgement Receipt**

<b>EFS ID:</b>	31418840
<b>Application Number:</b>	15705172
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	2879
<b>Title of Invention:</b>	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF
<b>First Named Inventor/Applicant Name:</b>	Stephen Donald WILTON
<b>Customer Number:</b>	123147
<b>Filer:</b>	Amy E. Mandragouras/Anita Costa
<b>Filer Authorized By:</b>	Amy E. Mandragouras
<b>Attorney Docket Number:</b>	AVN-008CN41
<b>Receipt Date:</b>	05-JAN-2018
<b>Filing Date:</b>	14-SEP-2017
<b>Time Stamp:</b>	16:34:08
<b>Application Type:</b>	Utility under 35 USC 111(a)

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	EPO_Comm_Decsion_from_OD_dated_19_Dec_2017.PDF	1601222	no	23
			c83843dd51298fe3a40cb40bda5ae36c43624a3b		
Warnings:					
Information:					
2	Non Patent Literature	EESR_AVN_009EPDV2.pdf	202097	no	7
			cfe1d6db14b304495624a8d9c867c6165f4e8754		
Warnings:					
Information:					
3	Non Patent Literature	EESR_008EPDV5.PDF	318700	no	10
			626dd3b5b8841cce22bb9922016be0c3684ac2477		
Warnings:					
Information:					
4	Non Patent Literature	106007_DOC215.pdf	31278	no	2
			a85666f914d6bdc9f402afc21b8dbec1fce15822		
Warnings:					
Information:					
5	Other Reference-Patent/App/Search documents	14776533_02.pdf	746034	no	24
			0f37cd3fbf4e8bacf801363122b0e4cb4d33be9f		
Warnings:					
Information:					
6	Other Reference-Patent/App/Search documents	15359152.pdf	228974	no	9
			f2776441936bb0162cd66ed709480c568f0cc304		
Warnings:					
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7	Other Reference-Patent/App/Search documents	15417401.pdf	359713 0dcff7a1d291f8d7459f13ac48cf05141e494e84	no	13
<b>Warnings:</b>					
<b>Information:</b>					
8	Other Reference-Patent/App/Search documents	15420823.pdf	202848 d54128e633ebb97e95c3be278715d057303c0400	no	8
<b>Warnings:</b>					
<b>Information:</b>					
9	Other Reference-Patent/App/Search documents	15422127.pdf	396508 96dded42c5f92fc1ffb473a51e6f21e71b03928e	no	15
<b>Warnings:</b>					
<b>Information:</b>					
10	Information Disclosure Statement (IDS) Form (SB08)	SB08_02.pdf	1059785 052e694073ccf52738f55bd75a0d013df2f70ec0	no	5
<b>Warnings:</b>					
<b>Information:</b>					
11	Information Disclosure Statement (IDS) Form (SB08)	IDSTRANS.pdf	33954 6db9b3bfe64371a046336d29cee5697246798181	no	3
<b>Warnings:</b>					
<b>Information:</b>					
This is not an USPTO supplied IDS fillable form					
12	Fee Worksheet (SB06)	fee-info.pdf	30688 5106089018ed7706631ae6ad29940f834ac57004	no	2
<b>Warnings:</b>					
<b>Information:</b>					
<b>Total Files Size (in bytes):</b>			5211801		

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**New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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## TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA/82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	15/705,172
Filing Date	September 14, 2017
First Named Inventor	Stephen Donald WILTON
Title	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF
Art Unit	1674
Examiner Name	CHONG, Kimberly
Attorney Docket Number	4140.01500A9

### SIGNATURE of Applicant or Patent Practitioner

Signature	<i>Marsha Rose Gillentine</i>	Date (Optional)	<i>March 28, 2018</i>
Name	Marsha Rose Gillentine	Registration Number	58,403
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

**NOTE:** This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐

\*Total of \_\_\_\_\_ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

SRPT-VYDS-0004929



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Document Description: Power of Attorney

PTO/AIA/82B (07-13)  
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## POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date
15/705,172	September 14, 2017

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☒ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above:

153767

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☒ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

153767

OR

Firm or Individual Name			
Address			
City	State	Zip	
Country			
Telephone	Email		

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

THE UNIVERSITY OF WESTERN AUSTRALIA

- ☐ Inventor or Joint Inventor (title not required below)
- ☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)
- ☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)
- ☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

### SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	<i>Robyn Owens</i>	Date (Optional)
Name	Professor Robyn Owens	
Title	Deputy Vice-Chancellor (Research)	

**NOTE:** Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☒ Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**Electronic Acknowledgement Receipt**

<b>EFS ID:</b>	32177928
<b>Application Number:</b>	15705172
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	2879
<b>Title of Invention:</b>	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF
<b>First Named Inventor/Applicant Name:</b>	Stephen Donald WILTON
<b>Customer Number:</b>	123147
<b>Filer:</b>	Marsha Rose Gillentine
<b>Filer Authorized By:</b>	
<b>Attorney Docket Number:</b>	AVN-008CN41
<b>Receipt Date:</b>	28-MAR-2018
<b>Filing Date:</b>	14-SEP-2017
<b>Time Stamp:</b>	16:23:18
<b>Application Type:</b>	Utility under 35 USC 111(a)

**Payment information:**

Submitted with Payment	no
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**File Listing:**

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	4140_01500A9_Filing_POA.pdf	332996 e448cc9f9b39512a8ca09f37e7466c5ba4d6bfa8c	no	2

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332996

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**New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/705,172	09/14/2017	Stephen Donald WILTON	4140.01500A9

**CONFIRMATION NO. 2879**

**POA ACCEPTANCE LETTER**

153767  
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.  
1100 NEW YORK AVENUE, N.W.  
WASHINGTON, DC 20005



\*OC000000098475974\*

Date Mailed: 04/02/2018

**NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY**

This is in response to the Power of Attorney filed 03/28/2018.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/nbekele/



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/705,172	09/14/2017	Stephen Donald WILTON	AVN-008CN41

**CONFIRMATION NO. 2879**

**POWER OF ATTORNEY NOTICE**



\*OC000000098475952\*

Date Mailed: 04/02/2018

123147  
Nelson Mullins Riley & Scarborough LLP/Sarepta  
One Post Office Square  
Boston, MA 02109

**NOTICE REGARDING CHANGE OF POWER OF ATTORNEY**

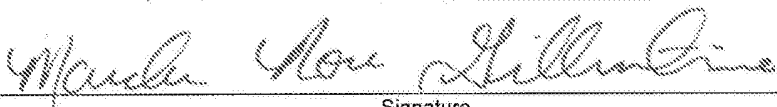
This is in response to the Power of Attorney filed 03/28/2018.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/nbekele/

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<b>TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT</b>	Docket Number (Optional) <b>4140.01500A9</b>
<p>In re Application of: <b>The University of Western Australia</b></p> <p>Application No.: <b>15/705,172</b></p> <p>Filed: <b>September 14, 2017</b></p> <p>For: <b>ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF</b></p> <p>The applicant, <u>The University of Western Australia</u>, owner of <u>100</u> percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of <b>prior patent</b> No. <u>8,232,384 B2</u> as the term of said <b>prior patent</b> is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the <b>prior patent</b> are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.</p> <p>In making the above disclaimer, the applicant does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the <b>prior patent</b>, "as the term of said <b>prior patent</b> is presently shortened by any terminal disclaimer," in the event that said <b>prior patent</b> later:</p> <ul style="list-style-type: none"> <li>expires for failure to pay a maintenance fee;</li> <li>is held unenforceable;</li> <li>is found invalid by a court of competent jurisdiction;</li> <li>is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;</li> <li>has all claims canceled by a reexamination certificate;</li> <li>is reissued; or</li> <li>is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.</li> </ul> <p>Check either box 1 or 2 below, if appropriate.</p> <p>1. <input type="checkbox"/> The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.</p> <p>I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.</p> <p>2. <input checked="" type="checkbox"/> The undersigned is an attorney or agent of record. Reg. No. <u>58,403</u></p> <div style="margin-top: 20px;"> <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;">               Signature         </div> <div style="text-align: center;"> <u>April 3, 2018</u>              Date         </div> </div> <div style="text-align: center; margin-top: 10px;"> <b>Marsha Rose Gillentine</b>              Typed or printed name         </div> <div style="display: flex; justify-content: space-between; margin-top: 20px;"> <div style="text-align: center;">             Director              _____              Title         </div> <div style="text-align: center;"> <u>(202) 371-2600</u>              Telephone Number         </div> </div> </div> <p><input checked="" type="checkbox"/> Terminal disclaimer fee under 37 CFR 1.20(d) included.</p> <p style="text-align: center;"><b>WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</b></p>	

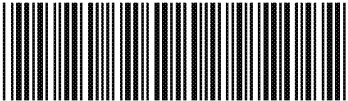
This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

9204086

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

SRPT-VYDS-0004935

# 33028

<b><i>Search Notes</i></b> 	<b>Application/Control No.</b> 15/705,172	<b>Applicant(s)/Patent Under Reexamination</b> WILTON et al.
	<b>Examiner</b> KIMBERLY CHONG	<b>Art Unit</b> 1674

<b>CPC - Searched*</b>		
<b>Symbol</b>	<b>Date</b>	<b>Examiner</b>
C07H 21/04	9/29/2017	KC

<b>CPC Combination Sets - Searched*</b>		
<b>Symbol</b>	<b>Date</b>	<b>Examiner</b>

<b>US Classification - Searched*</b>			
<b>Class</b>	<b>Subclass</b>	<b>Date</b>	<b>Examiner</b>

\* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

<b>Search Notes</b>		
<b>Search Notes</b>	<b>Date</b>	<b>Examiner</b>
SEQ ID No. 195	9/29/2017	KC
PALM inventor name search	9/29/2017	KC
updated	03/21/2018	KC

<b>Interference Search</b>			
<b>US Class/CPC Symbol</b>	<b>US Subclass/CPC Group</b>	<b>Date</b>	<b>Examiner</b>

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/705,172	09/14/2017	Stephen Donald WILTON	4140.01500A9	2879
153767	7590	04/04/2018		
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.			EXAMINER	
1100 NEW YORK AVENUE, N.W.			CHONG, KIMBERLY	
WASHINGTON, DISTRICT OF COLUMBIA 20005				
UNITED STATES OF AMERICA				
			ART UNIT	PAPER NUMBER
			1674	
			MAIL DATE	DELIVERY MODE
			04/04/2018	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Application No.

15/705,172

Applicant(s)

WILTON et al.

**Office Action Summary**

Examiner

KIMBERLY CHONG

Art Unit

1674

AIA Status

No

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01/05/2018.  
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims\***

- 5) ☒ Claim(s) 2-3 is/are pending in the application.  
 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 2-3 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement

\* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).

**Application Papers**

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

**Certified copies:**

- a) ☐ All b) ☐ Some\*\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)  
 Paper No(s)/Mail Date 01/05/2018.
- 3) ☒ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date 03/26/2018.
- 4) ☐ Other: \_\_\_\_.

Application/Control Number: 15/705,172  
Art Unit: 1674

Page 2

***Notice of Pre-AIA or AIA Status***

The present application is being examined under the pre-AIA first to invent provisions.

**DETAILED ACTION**

***Status of Application/Amendment/Claims***

Claims 2 and 3 are pending and currently under examination.

***Information Disclosure Statement***

The submission of the Information Disclosure Statements on 01/05/2018 is in compliance with 37 CFR 1.97. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

***Response to Arguments***

***Claim Rejections - 35 USC § 103***

The rejection of claims 2 and 3 under pre-AIA 35 U.S.C. 103(a) as being obvious over van Ommen (WO2004/083432 cited on IDS filed 09/22/2017) and Koenig et al. (Nature 338, 509 - 511 06 April 1989 cited on IDS filed 09/22/2017) is withdrawn in response to Applicant's argument that one of skill in the art would not have been motivated to make the claimed oligonucleotide from h53AON1 taught by van Ommen.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit [www.uspto.gov/forms/](http://www.uspto.gov/forms/). The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to

<http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-l.jsp>.

Application/Control Number: 15/705,172  
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The rejection of claims 2 and 3 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 8,455,636 is withdrawn in response to Applicant's arguments.

The rejection of claims 2 and 3 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 8,232,384 is maintained for the reasons of record.

Patent '384 are drawn to an antisense oligonucleotide targeted to annealing site H53A (+23+47) and consisting of SEQ ID No. 195 which is 25 nucleotides in length. The instant claims are drawn to an antisense oligonucleotide targeted to annealing site H53A (+23+47) having 20-31 bases comprising at least 12 consecutive bases of SEQ ID No. 195 but could also encompass 25 nucleotides of SEQ ID No. 195. Therefore the instant claims and the claims of the patent are not patentably distinct from each other.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Application/Control Number: 15/705,172  
Art Unit: 1674

Page 5

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KIMBERLY CHONG **whose telephone number is** (571)272-3111. The examiner can normally be reached Monday thru Friday 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Ram Shukla at 571-272-07350735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Application/Control Number: 15/705,172  
Art Unit: 1674

Page 6

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/  
Primary Examiner  
Art Unit 1674



# 33036

<b><i>Examiner-Initiated Interview Summary</i></b>	<b>Application No.</b> 15/705,172		<b>Applicant(s)</b> WILTON et al.	
	<b>Examiner</b> KIMBERLY CHONG		<b>Art Unit</b> 1674	<b>AIA Status</b> No

All participants (applicant, applicant's representative, PTO personnel):

(1) KIMBERLY CHONG. (3) \_\_\_\_\_.

(2) AMY MANDRAGOURAS. (4) \_\_\_\_\_.

Date of Interview: 27 March 2018.

Type: ☒ Telephonic ☐ Video Conference  
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.  
If Yes, brief description: \_\_\_\_\_.

Issues Discussed ☐ 101 ☐ 112 ☐ 102 ☐ 103 ☐ Others  
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: \_\_\_\_\_.

Identification of prior art discussed: \_\_\_\_\_.

**Substance of Interview**  
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Called to tell Applicant's that the 103 rejection is withdrawn and to discuss double patenting rejection and whether Applicant's would file an eTerminal disclaimer since that is the only remaining rejection. I was informed this application has been transferred to a new law firm..

**Applicant recordation instructions:** It is not necessary for applicant to provide a separate record of the substance of interview.

**Examiner recordation instructions:** Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/KIMBERLY CHONG/ Primary Examiner, Art Unit 1674	
---	--

Doc code: IDS

# 33037

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2016. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number	15705172
	Filing Date	2017-09-14
	First Named Inventor	Stephen Donald WILTON
	Art Unit	1674
	Examiner Name	K. Chong
	Attorney Docket Number	AVN-008CN41

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	9758783		2017-09-12	Wilton et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20110046203	A1	2011-02-24	Wilton et al.	
	2	20170283799	A1	2017-10-05	KAYE	
	3	20170292125	A1	2017-10-12	SAZANI et al.	
	4	20170369875	A1	2017-12-28	BESTWICK et al.	
	5	20170369876	A1	2017-12-28	BESTWICK et al.	

Application Number # 33038		15705172
Filing Date		2017-09-14
First Named Inventor	Stephen Donald WILTON	
Art Unit	1674	
Examiner Name	K. Chong	
Attorney Docket Number	AVN-008CN41	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

	6	20180002689	A1	2018-01-04	BESTWICK et al.	
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If you wish to add additional U.S. Published Application citation information please click the Add button.

**FOREIGN PATENT DOCUMENTS**

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup>	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1							

If you wish to add additional Foreign Patent Document citation information please click the Add button.

**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1	European Decision of the Opposition Division, European Application No. 10004274.6, dated December 19, 2017, 23 pages.	
	2	Extended European Search Report, EP 16172354.9, dated January 23, 2017, 7 pages.	
	3	Extended European Search Report, EP 17159328.8, dated September 5, 2017, 10 pages.	
	4	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Filing Priority Statement, 2 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 215)	

If you wish to add additional non-patent literature document citation information please click the Add button.

**EXAMINER SIGNATURE**

Examiner Signature	/KIMBERLY CHONG/ (04/02/2018)	Date Considered	
--------------------	-------------------------------	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	K. Chong
Attorney Docket Number	AVN-008CN41

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

Application Number # 33040	15705172
Filing Date	2017-09-14
First Named Inventor	Stephen Donald WILTON
Art Unit	1674
Examiner Name	K. Chong
Attorney Docket Number	AVN-008CN41

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

- ☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☒ A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Amy E. Mandragouras, Esq./	Date (YYYY-MM-DD)	2018-01-05
Name/Print	Amy E. Mandragouras, Esq.	Registration Number	36,207

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

## NOTICE OF ALLOWANCE AND FEE(S) DUE

153767 7590 04/26/2018  
 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.  
 1100 NEW YORK AVENUE, N.W.  
 WASHINGTON, DISTRICT OF COLUMBIA 20005  
 UNITED STATES OF AMERICA

EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1674

DATE MAILED: 04/26/2018

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/705,172	09/14/2017	Stephen Donald WILTON	4140.01500A9	2879

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0.00	\$0.00	\$500	07/26/2018

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.**

## HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**



PART B - FEE(S) TRANSMITTAL  
#: 33043

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**  
**Commissioner for Patents**  
**P.O. Box 1450**  
**Alexandria, Virginia 22313-1450**  
**or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

153767 7590 04/26/2018  
 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.  
 1100 NEW YORK AVENUE, N.W.  
 WASHINGTON, DISTRICT OF COLUMBIA 20005  
 UNITED STATES OF AMERICA

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

**Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/705,172	09/14/2017	Stephen Donald WILTON	4140.01500A9	2879

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0.00	\$0.00	\$500	07/26/2018

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHONG, KIMBERLY	1674	536-024500

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). <input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. <input type="checkbox"/> "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. <b>Use of a Customer Number is required.</b>	2. For printing on the patent front page, list (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.	1 _____ 2 _____ 3 _____
--	---	-------------------------------

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee  
☐ Publication Fee (No small entity discount permitted)  
☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.  
☐ Payment by credit card. Form PTO-2038 is attached.  
☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29  
☐ Applicant asserting small entity status. See 37 CFR 1.27  
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.  
 NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.  
 NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature \_\_\_\_\_ Date \_\_\_\_\_  
 Typed or printed name \_\_\_\_\_ Registration No. \_\_\_\_\_



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/705,172	09/14/2017	Stephen Donald WILTON	4140.01500A9	2879

153767 7590 04/26/2018  
 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.  
 1100 NEW YORK AVENUE, N.W.  
 WASHINGTON, DISTRICT OF COLUMBIA 20005  
 UNITED STATES OF AMERICA

EXAMINER
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CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
----------	--------------

1674

DATE MAILED: 04/26/2018

**Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**  
 (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

## OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

### Privacy Act Statement

**The Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

<b>Notice of Allowability</b>	<b>Application No.</b> 15/705,172	<b>Applicant(s)</b> WILTON et al.	
	<b>Examiner</b> KIMBERLY CHONG	<b>Art Unit</b> 1674	<b>AIA Status</b> No

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 04/04/2018.  
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on \_\_\_\_\_.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_\_; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 2-3. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

**Certified copies:**

a) ☐ All      b) ☐ Some      \*c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.  
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. <input type="checkbox"/> Notice of References Cited (PTO-892)	5. <input type="checkbox"/> Examiner's Amendment/Comment
2. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.	6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance
3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.	7. <input type="checkbox"/> Other _____.
4. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date. <u>04/09/2018</u> .	

/KIMBERLY CHONG/ Primary Examiner, Art Unit 1674	
---	--

Application/Control Number: 15/705,172  
Art Unit: 1674

Page 2

***Notice of Pre-AIA or AIA Status***

The present application is being examined under the pre-AIA first to invent provisions.

The following is an examiner's statement of reasons for allowance: the Terminal Disclaimer filed 04/04/2018 is approved and overcomes the Double Patenting Rejection of claims 2 and 3.

Claims 2 and 3 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **KIMBERLY CHONG** whose telephone number is (571)272-3111. The examiner can normally be reached Monday thru Friday between M-F 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Ram Shukla at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now

Application/Control Number: 15/705,172  
Art Unit: 1674

Page 3

contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/  
Primary Examiner  
Art Unit 1674

# 33049

<b><i>Applicant-Initiated Interview Summary</i></b>	<b>Application No.</b> 15/705,172	<b>Applicant(s)</b> WILTON et al.	
	<b>Examiner</b> KIMBERLY CHONG	<b>Art Unit</b> 1674	<b>AIA Status</b> No

All participants (applicant, applicants representative, PTO personnel):

(1) KIMBERLY CHONG. (3) \_\_\_\_.

(2) NEIL SHULL. (4) \_\_\_\_.

Date of Interview: 09 April 2018.

Type: ☒ Telephonic ☐ Video Conference  
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.  
If Yes, brief description: \_\_\_\_.

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☒Others  
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: \_\_\_\_.

Identification of prior art discussed: \_\_\_\_.

**Substance of Interview**  
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Confirmed that the Terminal Disclaimer was filed and approved. Claims 2 and 3 are in condition for allowance.

**Applicant recordation instructions:** The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

**Examiner recordation instructions:** Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/KIMBERLY CHONG/ Primary Examiner, Art Unit 1674	
---	--



# 33050  
**Summary of Record of Interview Requirements**

**Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record**

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

**Title 37 Code of Federal Regulations (CFR) 1.133 Interviews**

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiners responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicants correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

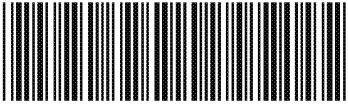
- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
 (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicants record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

**Examiner to Check for Accuracy**

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiners version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, Interview Record OK on the paper recording the substance of the interview along with the date and the examiners initials.

# 33051

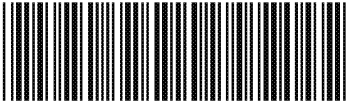
<b>Issue Classification</b> 	<b>Application/Control No.</b> 15/705,172	<b>Applicant(s)/Patent Under Reexamination</b> WILTON et al.
	<b>Examiner</b> KIMBERLY CHONG	<b>Art Unit</b> 1674

CPC						
Symbol					Type	Version
C12N	/	15	/	113	F	2013-01-01
C12N	/	2320	/	30	A	2013-01-01
C12N	/	2310	/	3341	A	2013-01-01
C12N	/	2310	/	321	A	2013-01-01
C12N	/	2310	/	315	A	2013-01-01
C12N	/	2310	/	3519	A	2013-01-01
C12N	/	2310	/	3233	A	2013-01-01
C12N	/	2310	/	11	A	2013-01-01
C12N	/	2320	/	33	A	2013-01-01
C12N	/	2310	/	33	A	2013-01-01

CPC Combination Sets				
Symbol	Type	Set	Ranking	Version
/				

NONE	<b>Total Claims Allowed:</b>	
(Assistant Examiner)	(Date)	2
/KIMBERLY CHONG/ Primary Examiner, Art Unit 1674	14 April 2018	O.G. Print Claim(s)
(Primary Examiner)	(Date)	1
		O.G. Print Figure none

# 33052

<b><i>Issue Classification</i></b> 	<b>Application/Control No.</b> 15/705,172	<b>Applicant(s)/Patent Under Reexamination</b> WILTON et al.
	<b>Examiner</b> KIMBERLY CHONG	<b>Art Unit</b> 1674

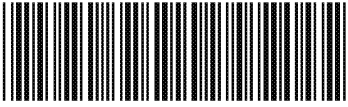
<b>INTERNATIONAL CLASSIFICATION</b>			
<b>CLAIMED</b>			
C07H	/	21	/ 04
<b>NON-CLAIMED</b>			
	/		/

<b>US ORIGINAL CLASSIFICATION</b>	
<b>CLASS</b>	<b>SUBCLASS</b>
536	24.5

<b>CROSS REFERENCES(S)</b>						
<b>CLASS</b>	<b>SUBCLASS (ONE SUBCLASS PER BLOCK)</b>					

NONE		<b>Total Claims Allowed:</b>	
(Assistant Examiner)	(Date)	2	
/KIMBERLY CHONG/ Primary Examiner, Art Unit 1674	14 April 2018	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	none

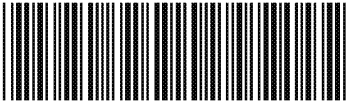
# 33053

<b>Issue Classification</b> 	<b>Application/Control No.</b> 15/705,172	<b>Applicant(s)/Patent Under Reexamination</b> WILTON et al.
	<b>Examiner</b> KIMBERLY CHONG	<b>Art Unit</b> 1674

<input checked="" type="checkbox"/> Claims renumbered in the same order as presented by applicant <input type="checkbox"/> CPA <input checked="" type="checkbox"/> T.D. <input type="checkbox"/> R.1.47															
<b>CLAIMS</b>															
<b>Final</b>	<b>Original</b>	<b>Final</b>	<b>Original</b>	<b>Final</b>	<b>Original</b>	<b>Final</b>	<b>Original</b>	<b>Final</b>	<b>Original</b>	<b>Final</b>	<b>Original</b>	<b>Final</b>	<b>Original</b>	<b>Final</b>	<b>Original</b>

NONE		<b>Total Claims Allowed:</b>	
(Assistant Examiner)	(Date)	2	
/KIMBERLY CHONG/ Primary Examiner, Art Unit 1674 (Primary Examiner)	14 April 2018 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure none

# 33054

<b><i>Search Notes</i></b> 	<b>Application/Control No.</b> 15/705,172	<b>Applicant(s)/Patent Under Reexamination</b> WILTON et al.
	<b>Examiner</b> KIMBERLY CHONG	<b>Art Unit</b> 1674

<b>CPC - Searched*</b>		
<b>Symbol</b>	<b>Date</b>	<b>Examiner</b>
C07H 21/04	9/29/2017	KC

<b>CPC Combination Sets - Searched*</b>		
<b>Symbol</b>	<b>Date</b>	<b>Examiner</b>

<b>US Classification - Searched*</b>			
<b>Class</b>	<b>Subclass</b>	<b>Date</b>	<b>Examiner</b>

\* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

<b>Search Notes</b>		
<b>Search Notes</b>	<b>Date</b>	<b>Examiner</b>
SEQ ID No. 195	9/29/2017	KC
PALM inventor name search	9/29/2017	KC
updated	04/09/2018	KC

<b>Interference Search</b>			
<b>US Class/CPC Symbol</b>	<b>US Subclass/CPC Group</b>	<b>Date</b>	<b>Examiner</b>
536	24.5	04/09/2018	KC

--	--

## PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** Mail Stop ISSUE FEE  
**Commissioner for Patents**  
**P.O. Box 1450**  
**Alexandria, Virginia 22313-1450**  
 or **Fax** (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

153767 7590 04/26/2018  
 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.  
 1100 NEW YORK AVENUE, N.W.  
 WASHINGTON, DISTRICT OF COLUMBIA 20005  
 UNITED STATES OF AMERICA

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

## Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/705,172	09/14/2017	Stephen Donald WILTON	4140.01500A9	2879

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0.00	\$0.00	\$500	07/26/2018

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHONG, KIMBERLY	1674	536-024500

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 \_\_\_\_\_  
 2 Sterne, Kessler, Goldstein  
 & Fox P.L.L.C.  
 3 \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

The University of Western Australia

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Crawley, Australia

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☒ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

☐ A check is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 19-0036 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature

Date

Typed or printed name

Eric K. Steffe

Registration No.

36,688

**Electronic Acknowledgement Receipt**

<b>EFS ID:</b>	32457433
<b>Application Number:</b>	15705172
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	2879
<b>Title of Invention:</b>	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF
<b>First Named Inventor/Applicant Name:</b>	Stephen Donald WILTON
<b>Customer Number:</b>	153767
<b>Filer:</b>	Neil P. Shull/Debbie Colonna
<b>Filer Authorized By:</b>	Neil P. Shull
<b>Attorney Docket Number:</b>	4140.01500A9
<b>Receipt Date:</b>	26-APR-2018
<b>Filing Date:</b>	14-SEP-2017
<b>Time Stamp:</b>	17:27:27
<b>Application Type:</b>	Utility under 35 USC 111(a)

**Payment information:**

Submitted with Payment	no
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**File Listing:**

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	4140_01500A9_Filing_IssueFee.pdf	1007577 3747e1587b1b47d7367c0190dc44b5d5340e423e	no	1

**Warnings:**



**Information:****Total Files Size (in bytes):**

1007577

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

**New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

**To:** e-office@sternekessler.com,jcovert@sternekessler.com,  
**From:** PAIR\_eOfficeAction@uspto.gov  
**Cc:** PAIR\_eOfficeAction@uspto.gov  
**Subject:** Private PAIR Correspondence Notification for Customer Number 153767

Apr 26, 2018 03:49:35 AM

Dear PAIR Customer:

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.  
1100 NEW YORK AVENUE, N.W.  
WASHINGTON, DC 20005  
UNITED STATES

The following USPTO patent application(s) associated with your Customer Number, 153767 , have new outgoing correspondence. This correspondence is now available for viewing in Private PAIR.

The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

**Disclaimer:**

The list of documents shown below is provided as a courtesy and is not part of the official file wrapper. The content of the images shown in PAIR is the official record.

Application	Document	Mailroom Date	Attorney Docket No.
15705172	NOA	04/26/2018	4140.01500A9
	INTV.SUM.APP	04/26/2018	4140.01500A9

To view your correspondence online or update your email addresses, please visit us anytime at <https://sportal.uspto.gov/secure/myportal/privatepair>.

If you have any questions, please email the Electronic Business Center (EBC) at [EBC@uspto.gov](mailto:EBC@uspto.gov) with 'e-Office Action' on the subject line or call 1-866-217-9197 during the following hours:

Monday - Friday 6:00 a.m. to 12:00 a.m.

Thank you for prompt attention to this notice,

UNITED STATES PATENT AND TRADEMARK OFFICE  
PATENT APPLICATION INFORMATION RETRIEVAL SYSTEM

APR-26-2018 18:54

SKGF

202 371 2540 P.001

ERIC K. STEFFE  
DIRECTOR  
(202) 772-8625  
ESTERPE@STERNEKESSLER.COM

RECEIVED  
CENTRAL FAX CENTER  
APR 26 2018

**Fax**

☒ Urgent

☐ Return reply requested

☐ Original will be sent as confirmation

To: USPTO

Date: April 26, 2018

Attention: USPTO Fee Payment

Re: Appl. No. 15/705,172; Filed 09/14/17  
For: ANTISENSE OLIGONUCLEOTIDES FOR  
INDUCING EXON SKIPPING AND  
METHODS OF USE THEREOF  
Inventors: WILTON et al.

From: Debbie Colonna

Pages (including cover sheet): 2

Fax No: 571-273-8300

Our Reference: 4140.01500A9

---

## Message

Submission of Issue Fee Payment (small entity) for Appl. No. 15/705,172

### Certification of Facsimile Transmission

I hereby certify that this paper is being facsimile transmitted  
to the Patent and Trademark Office on the date shown below.

Debbie Colonna  
Name  
Date: 4/26/2018

---

If any portion of this transmission is not received clearly or in full, contact us at the numbers below.

---

This message is intended for the exclusive use of the individual or entity to which it is addressed. The message may contain information that is privileged, confidential, or otherwise exempt from disclosure under applicable law. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution, copying or use of this communication in any way is strictly prohibited. If you have received this communication in error, please call us collect immediately, and return the original message to us at the above address via the U.S. Postal Service.

---

## PART B - FEE(S) TRANSMITTAL



Complete and send this form, together with applicable fee(s), to: **Mail Stop ISSUE FEE**  
**Commissioner for Patents**  
**P.O. Box 1450**  
**Alexandria, Virginia 22313-1450**  
 or Fax (571)-273-2885

**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All funds for correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

153767 7590 04/26/2018  
**STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.**  
 1100 NEW YORK AVENUE, N.W.  
 WASHINGTON, DISTRICT OF COLUMBIA 20005  
 UNITED STATES OF AMERICA

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

## Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/705,172	09/14/2017	Stephen Donald WILTON	4140.01500A9	2879

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0.00	\$0.00	\$500	07/26/2018

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHONG, KIMBERLY	1674	536-024500

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SD/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1. Sterne, Kessler, Goldstein  
 2. & Fox P.L.L.C.  
 3. \_\_\_\_\_

## 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

The University of Western Australia

(B) RESIDENCE (CITY and STATE OR COUNTRY)

Crawley, Australia

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☒ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

☐ A check is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 19-0036 (enclose an extra copy of this form).

## 5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29.

☐ Applicant asserting small entity status. See 37 CFR 1.27.

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment. NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature

Date

Typed or printed name Eric K. Steffe

Registered 04/26/2018 136688 00000024 190036 15705172



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/705,172	09/14/2017	Stephen Donald WILTON	4140.01500A9	2879

7590 05/03/2018  
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.  
1100 NEW YORK AVENUE, N.W.  
WASHINGTON, DC 20005

EXAMINER

CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
----------	--------------

1674

DATE MAILED: 05/03/2018

### PRIORITY ACKNOWLEDGMENT

- ☐ 1. Receipt is acknowledged of priority papers submitted under 35 U.S.C. 119. The papers have been placed of record in the file.
- ☒ 2. Applicant's claim for priority, based on papers filed in parent Application Number 11/570,691 submitted under 35 U.S.C. 119, is acknowledged.
- ☐ 3. The priority papers, submitted \_\_\_\_\_, after payment of the issue fee are
- ☐ acknowledged  
While the priority claim or certified copy filed will be placed in the file record, neither will be reviewed and the patent when published will not include the priority claim.  
See 37 CFR 1.55(a)(2).
  - ☐ not acknowledged since the processing fee in 37 CFR 1.17(i) has not been received.
- ☐ 4. For utility and plant applications filed on or after November 29, 2000, the priority claim is not entered because the claim was not presented within the time limit required by 37 CFR 1.55(a)(1). A petition to accept a delayed claim for priority under 35 U.S.C. 119(a) - (d) or (f), or 365(a) may be filed. See 37 CFR 1.55(c) and MPEP 201.14(a).

*24/11/2018, For*

571-272-4200 or 1-888-786-0101  
Application Assistance Unit  
Office of Data Management

**To:** e-office@sternekessler.com,jcovert@sternekessler.com,  
**From:** PAIR\_eOfficeAction@uspto.gov  
**Cc:** PAIR\_eOfficeAction@uspto.gov  
**Subject:** Private PAIR Correspondence Notification for Customer Number 153767

May 05, 2018 07:36:42 AM

Dear PAIR Customer:

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.  
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UNITED STATES

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Application	Document	Mailroom Date	Attorney Docket No.
15705172	M327	05/03/2018	4140.01500A9

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/705,172	06/12/2018	9994851	4140.01500A9	2879

153767 7590 05/23/2018  
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.  
1100 NEW YORK AVENUE, N.W.  
WASHINGTON, DC 20005

## ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

### **Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)** (application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

The University of Western Australia, Crawley, AUSTRALIA;  
Stephen Donald WILTON, Applecross, AUSTRALIA;  
Sue FLETCHER, Bayswater, AUSTRALIA;  
Graham MCCLOREY, Bayswater, AUSTRALIA;

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**Subject:** Private PAIR Correspondence Notification for Customer Number 153767

May 24, 2018 04:04:25 AM

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Application	Document	Mailroom Date	Attorney Docket No.
15705172	ISSUE.NTF	05/23/2018	4140.01500A9

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: WILTON *et al.*

Confirmation No.: 2879

Applicant: The University of Western  
Australia

Art Unit: 1674

Application No.: 15/705,172

Examiner: Chong, Kimberly

Filing Date: September 14, 2017

Atty. Docket: 4140.01500A9

Title: **ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND  
METHODS OF USE THEREOF**

**Statement of Substance of Interview  
In Accordance With 37 C.F.R. § 1.133(b) and M.P.E.P. § 713.04**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

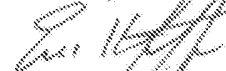
Commissioner:

In reply to the Interview Summary (Form PTOL-413) mailed by the U.S. Patent & Trademark Office with the Notice of Allowance on April 26, 2018, Applicant submits herewith the following Statement of Substance of the Interview held with Examiner Kimberly Chong, on April 9, 2018, regarding the above captioned application.

During the interview, the Examiner confirmed that the Terminal Disclaimer filed on April 3, 2018 was approved and that the application would be allowed.

Respectfully submitted,

STERNE, KESSLER, GOEDSTEIN & FOX P.L.L.C.



Eric K. Steffe

Attorney for Applicant  
Registration No. 36,688

Date: 5/29/18

1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600

9396506\_1.docx

**Electronic Acknowledgement Receipt**

<b>EFS ID:</b>	32743284
<b>Application Number:</b>	15705172
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	2879
<b>Title of Invention:</b>	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF
<b>First Named Inventor/Applicant Name:</b>	Stephen Donald WILTON
<b>Customer Number:</b>	153767
<b>Filer:</b>	Neil P. Shull/Debbie Colonna
<b>Filer Authorized By:</b>	Neil P. Shull
<b>Attorney Docket Number:</b>	4140.01500A9
<b>Receipt Date:</b>	29-MAY-2018
<b>Filing Date:</b>	14-SEP-2017
<b>Time Stamp:</b>	15:14:10
<b>Application Type:</b>	Utility under 35 USC 111(a)

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Submitted with Payment	no
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**File Listing:**

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant summary of interview with examiner	4140_01500A9_Filing_StatementSubstanceofInterview.pdf	407819 99efaf6ce36c6152beb4a1384d600e3f93a73e8b	no	1

**Warnings:**

**Information:****Total Files Size (in bytes):**

407819

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**National Stage of an International Application under 35 U.S.C. 371**

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/47 (03-09)

Approved for use through 05/31/2015. OMB 0651-0016

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For the following listed application(s), please recognize as the "Fee Address" under the provisions of 37 CFR 1.363 the address associated with:

☒ Customer Number: 154896

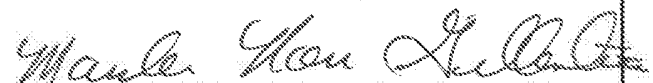
OR

☐ The attached Request for Customer Number (PTO/SB/125) form.

PATENT NUMBER (if known)	APPLICATION NUMBER
9,994,851	15/705,172

Completed by (check one):

☐ Applicant/Inventor

  
Signature

☒ Attorney or Agent of record 58,403  
(Reg. No.)

Marsha Rose Gillentine  
Typed or printed name

☐ Assignee of record of the entire interest. See 37 CFR 3.71.  
Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)

(202) 371-2600  
Requester's telephone number

☐ Assignee recorded at Reel \_\_\_\_\_ Frame \_\_\_\_\_

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

☐ \* Total of \_\_\_\_\_ forms are submitted.

This collection of information is required by 37 CFR 1.363. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 5 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop M Correspondence, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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SRPT-VYDS-0004985

**Electronic Acknowledgement Receipt**

<b>EFS ID:</b>	33011664
<b>Application Number:</b>	15705172
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	2879
<b>Title of Invention:</b>	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF
<b>First Named Inventor/Applicant Name:</b>	Stephen Donald WILTON
<b>Customer Number:</b>	153767
<b>Filer:</b>	Marsha Rose Gillentine
<b>Filer Authorized By:</b>	
<b>Attorney Docket Number:</b>	4140.01500A9
<b>Receipt Date:</b>	26-JUN-2018
<b>Filing Date:</b>	14-SEP-2017
<b>Time Stamp:</b>	18:24:28
<b>Application Type:</b>	Utility under 35 USC 111(a)

**Payment information:**

Submitted with Payment	no
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**File Listing:**

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	4140_01500A9_Fee_Address_Indication_Form.pdf	165669 9804f1317f83faa445c0b93a6b2ad6474a1548c7	no	1

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165669

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**National Stage of an International Application under 35 U.S.C. 371**

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**New International Application Filed with the USPTO as a Receiving Office**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent No.: 9,994,851

Confirmation No.: 2879

Date of Patent: June 12, 2018

Art Unit: 1674

Inventors: WILTON *et al.*

Atty. Docket: 4140.01500A9

Title: **ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF**

**Request for Certificate of Correction  
Under 37 C.F.R. § 1.323 For Applicant's Mistake**

*Attn: Certificate of Correction Branch*

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Commissioner:

It is hereby requested that a Certificate of Correction under 37 C.F.R. § 1.323 be issued for the above-captioned United States Patent. This Certificate of Correction is being requested due to mistakes which appear in the printed patent. The mistakes made by Inventors are of a clerical or typographical nature, or of a minor character. Patentees submit that correction of these errors does not introduce new matter.

Specifically, the printed patent contains the following errors for which a Certificate of Correction is respectfully requested:

**In the specification**

**Column 1, Line 26, before "STATEMENT REGARDING SEQUENCE LISTING", insert:**

**--STATEMENT AS TO FEDERALLY SPONSORED RESEARCH**

**This invention was made with government support under grant number R01 NS044146 awarded by the National Institutes of Health. The government has certain rights in the invention.--**

- 2 -

WILTON *et al.*  
U.S. Patent No. 9,994,851

***Remarks***

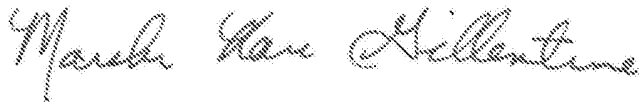
The above-noted corrections do not involve such changes in the patent as would constitute new matter or would require reexamination.

A completed Form PTO/SB/44 accompanies this request, with the above-noted corrections printed thereon. Accordingly, a Certificate of Correction is believed proper and issuance thereof is respectfully requested.

This request is accompanied by payment of the fee set forth in 37 C.F.R. § 1.20(a). Fee payment is provided through online credit card payment. The Commissioner is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Marsha Rose Gillentine  
Attorney for Patentees  
Registration No. 58,403

Date: June 29, 2018

1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600

9578306\_1.docx

SRPT-VYDS-0004989

**UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION**

Page 1 of 1

PATENT NO. : 9,994,851

APPLICATION NO. : 15/705,172

ISSUE DATE : June 12, 2018

INVENTOR(S) : WILTON *et al.*

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the specification

Column 1, Line 26, before "STATEMENT REGARDING SEQUENCE LISTING", insert:

--STATEMENT AS TO FEDERALLY SPONSORED RESEARCH

This invention was made with government support under grant number R01 NS044146 awarded by the National Institutes of Health. The government has certain rights in the invention.--

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SRPT-VYDS-0004990

Electronic Patent Application Fee Transmittal				
<b>Application Number:</b>		15705172		
<b>Filing Date:</b>		14-Sep-2017		
<b>Title of Invention:</b>		ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF		
<b>First Named Inventor/Applicant Name:</b>		Stephen Donald WILTON		
<b>Filer:</b>		Marsha Rose Gillentine/Beverly Swann		
<b>Attorney Docket Number:</b>		4140.01500A9		
Filed as Large Entity				
<b>Filing Fees for Utility under 35 USC 111(a)</b>				
<b>Description</b>	<b>Fee Code</b>	<b>Quantity</b>	<b>Amount</b>	<b>Sub-Total in USD(\$)</b>
<b>Basic Filing:</b>				
<b>Pages:</b>				
<b>Claims:</b>				
<b>Miscellaneous-Filing:</b>				
<b>Petition:</b>				
<b>Patent-Appeals-and-Interference:</b>				
<b>Post-Allowance-and-Post-Issuance:</b>				
CERTIFICATE OF CORRECTION	1811	1	150	150

# 33075

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				150

**Electronic Acknowledgement Receipt**

<b>EFS ID:</b>	33045562
<b>Application Number:</b>	15705172
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	2879
<b>Title of Invention:</b>	ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF
<b>First Named Inventor/Applicant Name:</b>	Stephen Donald WILTON
<b>Customer Number:</b>	153767
<b>Filer:</b>	Marsha Rose Gillentine/Beverly Swann
<b>Filer Authorized By:</b>	Marsha Rose Gillentine
<b>Attorney Docket Number:</b>	4140.01500A9
<b>Receipt Date:</b>	29-JUN-2018
<b>Filing Date:</b>	14-SEP-2017
<b>Time Stamp:</b>	13:04:06
<b>Application Type:</b>	Utility under 35 USC 111(a)

**Payment information:**

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 150
RAM confirmation Number	062918INTEFSW13042600
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

**File Listing:**

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	414001500A9Ptocover.pdf	260801	no	1
			88ce2cc4e2806e54a54265eb2620088de49d84cf		
Warnings:					
Information:					
2	Request for Certificate of Correction	414001500A9Request.pdf	140390	no	2
			505e877b7f4400beaba290056a09b206840c736c		
Warnings:					
Information:					
3	Request for Certificate of Correction	414001500A9COC.pdf	132779	no	1
			727d3a3f4034370a2970357ac31ce04c303b1f65		
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30421	no	2
			b2b1564d3e79221ee3ea74964264093ce7492c7f		
Warnings:					
Information:					
Total Files Size (in bytes):			564391		



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**New Applications Under 35 U.S.C. 111**

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**New International Application Filed with the USPTO as a Receiving Office**

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MARSHA ROSE GILLENTINE  
DIRECTOR  
(202) 772-8692  
MGILLENTINE@STERNEKESSLER.COM

June 29, 2018

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Confirmation No. 2879**  
**Art Unit 1674**

Re: U.S. Patent No. 9,994,851; Issue Date: June 12, 2018  
(from U.S. Appl. No. 15/705,172; Filing Date: September 14, 2017)  
For: **ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON  
SKIPPING AND METHODS OF USE THEREOF**  
Inventors: WILTON *et al.*  
Our Ref: 4140.01500A9

Commissioner:

Transmitted herewith for appropriate action are the following documents:

1. Online Credit Card Payment Authorization in the amount of \$150.00 to cover fee for Request for Certificate of Correction;
2. Request for Certificate of Correction Under 37 C.F.R. § 1.323 For Applicant's Mistake; and
3. Certificate of Correction (PTO/SB/44).

The above-listed documents are filed electronically.

Fee payment is provided through online credit card payment. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency or credit any overpayment to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in cursive script, reading "Marsha Rose Gillentine".

Marsha Rose Gillentine  
Attorney for Patentees  
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MRG/ABM/mwf  
Enclosures

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UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO. : 9,994,851 B2  
APPLICATION NO. : 15/705172  
DATED : June 12, 2018  
INVENTOR(S) : Wilton et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:


**In the Specification**

Column 1, Line 26, before "STATEMENT REGARDING SEQUENCE LISTING", insert:

--STATEMENT AS TO FEDERALLY SPONSORED RESEARCH

This invention was made with government support under grant number R01 NS044146 awarded by the National Institutes of Health. The government has certain rights in the invention.--

Signed and Sealed this  
Thirty-first Day of July, 2018



Andrei Iancu  
*Director of the United States Patent and Trademark Office*